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Presidential Documents

Title 3—

The President

Executive Order 13283 of January 21, 2003

Establishing the Office of Global Communications

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Establishment of the Office of Global Communications.* There is hereby established within the White House Office an Office of Global Communications (the ''Office'') to be headed by a Deputy Assistant to the President for Global Communications.

Sec. 2. *Mission.* The mission of the Office shall be to advise the President, the heads of appropriate offices within the Executive Office of the President, and the heads of executive departments and agencies (agencies) on utilization of the most effective means for the United States Government to ensure consistency in messages that will promote the interests of the United States abroad, prevent misunderstanding, build support for and among coalition partners of the United States, and inform international audiences. The Office shall provide such advice on activities in which the role of the United States Government is apparent or publicly acknowledged.

Sec. 3. *Functions.* In carrying out its mission:

(a) The Office shall assess the methods and strategies used by the United States Government (other than special activities as defined in Executive Order 12333 of December 4, 1981) to deliver information to audiences abroad. The Office shall coordinate the formulation among appropriate agencies of messages that reflect the strategic communications framework and priorities of the United States, and shall facilitate the development of a strategy among the appropriate agencies to effectively communicate such messages.

(b) The Office shall work with the policy and communications offices of agencies in developing a strategy for disseminating truthful, accurate, and effective messages about the United States, its Government and policies, and the American people and culture. The Office may, after consulting with the Department of State and obtaining the approval of the Assistant to the President for National Security Affairs on the President's behalf, work with cooperating foreign governments in the development of the strategy. In performing its work, the Office shall coordinate closely and regularly with the Assistant to the President for National Security Affairs, or the Assistant's designee.

(c) The Office shall work with appropriate agencies to coordinate the creation of temporary teams of communicators for short-term placement in areas of high global interest and media attention as determined by the Office. Team members shall include personnel from agencies to the extent permitted by law and subject to the availability of personnel. In performing its functions, each information team shall work to disseminate accurate and timely information about topics of interest to the on-site news media, and assist media personnel in obtaining access to information, individuals, and events that reinforce the strategic communications objectives of the United States and its allies. The Office shall coordinate when and where information teams should be deployed; provided, however, no information team shall be deployed abroad without prior consultation with the Department of State and the Department of Defense, and prior notification to the Office of the Assistant to the President for National Security Affairs.

(d) The Office shall encourage the use of state-of-the-art media and technology and shall advise the United States Government of events, technologies, and other communications tools that may be available for use in conveying information.

Sec. 4. *Administration.* The Office of Administration within the Executive Office of the President shall provide the Office with administrative and related support, to the extent permitted by law and subject to the availability of appropriations, as directed by the Chief of Staff to the President to carry out the provisions of this order.

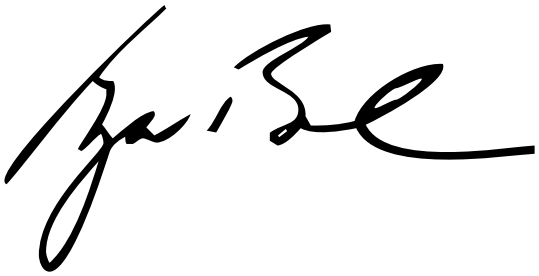
Sec. 5. *Relationship to Other Interagency Coordinating Mechanisms.* Presidential direction regarding National Security Council-related mechanisms for coordination of national security policy shall apply with respect to the Office in the same manner as it applies with respect to other elements of the White House Office. Nothing in this order shall be construed to impair or otherwise affect any function assigned by law or by the President to the National Security Council or to the Assistant to the President for National Security Affairs.

Sec. 6. *Continuing Authorities.* This order does not alter the existing authorities of any agency. Agencies shall assist the Deputy Assistant to the President for Global Communications, to the extent consistent with applicable law and direction of the President, and to the extent such assistance is consistent with national security objectives and with the mission of such agencies, in carrying out the Office's mission.

Sec. 7. *General Provisions.*

(a) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by any party against the United States, its agencies, instrumentalities or entities, its officers or employees, or any other person.

(b) Nothing in this order shall be construed to grant to the Office any authority to issue direction to agencies, officers, or employees.



THE WHITE HOUSE,
January 21, 2003.

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Rules and Regulations

Federal Register
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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 02–121–2]

Mexican Fruit Fly; Addition of Regulated Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are revising the Mexican fruit fly regulations by adding a portion of Los Angeles County, CA, to the existing regulated area and restricting the interstate movement of regulated articles from that area. This action is necessary to prevent the spread of the Mexican fruit fly into noninfested areas of the United States.

DATES: This interim rule was effective January 17, 2003. We will consider all comments that we receive on or before March 25, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–121–2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–121–2. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–121–2'' on the subject line.

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

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

FOR FURTHER INFORMATION CONTACT: Mr. Stephen A. Knight, Senior Staff Officer, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

The Mexican fruit fly (*Anastrepha ludens*) is a destructive pest of citrus and many other types of fruit. The short life cycle of the Mexican fruit fly allows rapid development of serious outbreaks that can cause severe economic losses in commercial citrus-producing areas.

The Mexican fruit fly regulations, contained in 7 CFR 301.64 through 301.64–10 (referred to below as the regulations), were established to prevent the spread of the Mexican fruit fly to noninfested areas of the United States. The regulations impose restrictions on the interstate movement of regulated articles from the regulated areas.

In an interim rule effective on December 13, 2002, and published in the **Federal Register** on December 23, 2002 (67 FR 78127–78128, Docket No. 02–121–1), we amended the regulations by adding a portion of Los Angeles County, CA, as a regulated area. Prior to the effective date of that rule, the only areas regulated for the Mexican fruit fly were portions of Texas. In this interim rule, we are designating an additional portion of Los Angeles County, CA, as a regulated area.

Section 301.64–3 provides that the Deputy Administrator for Plant Protection and Quarantine, Animal and Plant Health Inspection Service (APHIS), shall list as a regulated area each quarantined State, or each portion of a quarantined State, in which the Mexican fruit fly has been found by an inspector, in which the Deputy Administrator has reason to believe the Mexican fruit fly is present, or that the Deputy Administrator considers necessary to regulate because of its proximity to the Mexican fruit fly or its inseparability for quarantine enforcement purposes from localities in which the Mexican fruit fly occurs.

Less than an entire quarantined State is designated as a regulated area only if the Deputy Administrator determines that the State has adopted and is enforcing a quarantine or regulation that imposes restrictions on the intrastate movement of the regulated articles that are substantially the same as those that are imposed with respect to the interstate movement of the articles and the designation of less than the entire State as a regulated area will otherwise be adequate to prevent the artificial interstate spread of the Mexican fruit fly.

Recent trapping surveys by inspectors of California State and county agencies and by APHIS inspectors reveal that an additional portion of Los Angeles County, CA, is infested with the Mexican fruit fly.

Accordingly, to prevent the spread of the Mexican fruit fly to noninfested areas of the United States, we are amending the regulations in § 301.64–3 by adding that portion of Los Angeles County, CA, to the existing regulated area for the Mexican fruit fly. The addition is described in detail in the rule portion of this document. The Deputy Administrator has determined that it is not necessary to designate the entire State of California as a regulated area.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the Mexican fruit fly from spreading to noninfested areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments

we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

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

This rule restricts the interstate movement of regulated articles from an area in Los Angeles County, CA. Within the regulated area there are approximately 389 small entities that may be affected by this rule. These include 351 fruit sellers, 3 growers, 33 nurseries, 1 certified farmers' market, and 1 swapmeet. These 389 entities comprise less than 1 percent of the total number of similar entities operating in the State of California. Additionally, these small entities sell regulated articles primarily for local intrastate, not interstate, movement, so the effect, if any, of this rule on these entities appears to be minimal.

The effect on those few entities that do move regulated articles interstate will be minimized by the availability of various treatments that, in most cases, will allow these small entities to move regulated articles interstate with very little additional cost.

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

Executive Order 12372

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

Executive Order 12988

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

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this interim rule. The site-specific environmental assessment provides a basis for the conclusion that the implementation of integrated pest management to eradicate the Mexican fruit fly will not have a significant impact on human health and the natural environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this document). In addition, copies may be obtained from the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

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

List of Subjects in 7 CFR Part 301

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

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

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

Authority: 7 U.S.C. 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, 7754, and 7760; 7 CFR 2.22, 2.80, and 371.3.

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

2. In § 301.64–3, paragraph (c) , under the heading ''California'', the entry for Los Angeles County is revised to read as follows:

§ 301.64–3 Regulated areas.

* * * * *

(c) * * *

California

Los Angeles County. That portion of the county in the South Pasadena and Monterey Park areas bounded by a line as follows: Beginning at the intersection of Valley Boulevard and Peck Road; then south on Peck Road to Workman Mill Road; then southwest on Workman Mill Road to Norwalk Boulevard; then southwest on Norwalk Boulevard to Whittier Boulevard; then northwest on Whittier Boulevard to Passons Boulevard; then southwest on Passons Boulevard to Washington Boulevard; then northwest on Washington Boulevard to Paramount Boulevard; then southwest on Paramount Boulevard to East Slauson Avenue; then west on East Slauson Avenue to U.S. Interstate 710; then northwest on U.S. Interstate 710 to U.S. Interstate 5; then northwest on U.S. Interstate 5 to South Indiana Street; then north on South Indiana Street to North Indiana Street; then north on North Indiana Street to Cesar Chavez Avenue; then northwest on Cesar Chavez Avenue to North Soto Street; then north on North Soto Street to Valley Boulevard; then west on Valley Boulevard to North Main Street; then west on North Main Street to Daly Street; then north on Daly Street to Pasadena Avenue; then north on Pasadena Avenue to North Figueroa Street; then southwest on North Figueroa Street to Cypress Avenue; then northwest on Cypress Avenue to Eagle Rock Boulevard; then northeast on Eagle Rock Boulevard to Colorado Boulevard; then east on Colorado Boulevard to West Colorado Boulevard; then northeast on West Colorado Boulevard to State Highway 710; then north on State Highway 710 to U.S. Interstate 210; then north on U.S. Interstate 210 to West Washington Boulevard; then east on West Washington Boulevard to East Washington Boulevard; then southeast on East Washington Boulevard to East Sierra Madre Boulevard; then east on East Sierra Madre Boulevard to Sierra Madre Villa Avenue; then south on Sierra Madre Villa Avenue to North Rosemead Boulevard; then southeast on North Rosemead Boulevard to Rosemead Boulevard; then south on Rosemead Boulevard to Longden Avenue; then east on Longden Avenue to Encinita Avenue; then south on Encinita Avenue to Las Tunas Drive; then east on Las Tunas Drive to Temple City Boulevard; then south on Temple City Boulevard to Olive Street; then east on Olive Street to Baldwin Avenue; then south on Baldwin Avenue to Lower Azusa Road; then east on Lower Azusa Road to Arden Drive; then south on Arden Drive to Valley Boulevard; then southeast on Valley Boulevard to the point of beginning.

* * * * *

Done in Washington, DC, this 17th day of January 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–1609 Filed 1–23–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 354

[Docket No. 02–085–2]

AQI User Fees: Extension of Current Fees Beyond Fiscal Year 2002

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the regulations to ensure that fiscal year 2002 user fee rates remain in effect beyond fiscal year 2002 until the fees are revised.

EFFECTIVE DATE: The interim rule became effective on September 3, 2002.

FOR FURTHER INFORMATION CONTACT: For information concerning program operations, contact Mr. Jim Smith, Director, Port Operations, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 60, Riverdale, MD 20737–1236; (301) 734–8295. For information concerning rate development, contact Ms. Donna Ford, PPQ User Fees Section Head, FMD, MRPBS, APHIS, 4700 River Road Unit 54, Riverdale, MD 20737–1232; (301) 734–5901.

SUPPLEMENTARY INFORMATION:

Background

Section 2509(a) of the Food, Agriculture, Conservation, and Trade Act of 1990 (21 U.S.C. 136a), referred to below as the FACT Act, authorizes the Animal and Plant Health Inspection Service to collect user fees for agricultural quarantine and inspection (AQI) services. The FACT Act was amended by § 917 of the Federal Agricultural Improvement and Reform Act of 1996 (Pub. L. 104–127), on April 4, 1996.

In an interim rule effective and published in the **Federal Register** on September 3, 2002 (67 FR 56217–56218, Docket No. 02–085–1), we amended the user fee regulations in 7 CFR part 354 to ensure that fiscal year 2002 rates remain in effect beyond fiscal year 2002 until the fees are revised.

Comments on the interim rule were required to be received on or before November 4, 2002. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 7 CFR Part 354

Exports, Government employees, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Travel and transportation expenses.

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 354 and that was published at 67 FR 56217–56218 on September 3, 2002.

Authority: 7 U.S.C. 2260; 21 U.S.C. 136 and 136a; 49 U.S.C. 80503; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 16th day of January 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–1607 Filed 1–23–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

[Docket No. 02–117–3]

Exotic Newcastle Disease; Additions to Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the exotic Newcastle disease regulations by quarantining Clark County, NV, and a portion of Nye County, NV, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread exotic Newcastle disease from the quarantined area. This action is necessary on an emergency basis to prevent the spread of exotic Newcastle disease from the quarantined area.

DATES: This interim rule was effective January 17, 2003. We will consider all comments that we receive on or before March 25, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–117–3, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–117–3. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–117–3'' on the subject line.

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

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

FOR FURTHER INFORMATION CONTACT: Dr. Aida Boghossian, Senior Staff Veterinarian, Emergency Programs Staff, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

Exotic Newcastle disease (END) is a contagious and fatal viral disease affecting the respiratory, nervous, and digestive systems of birds and poultry. END is so virulent that many birds and poultry die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. END can infect and cause death even in vaccinated poultry.

The regulations in ''Subpart A—Exotic Newcastle Disease (END)'' (9 CFR 82.1 through 82.15, referred to below as the regulations) were established to prevent the spread of END in the United States in the event of an outbreak. In § 82.3, paragraph (a) provides that any area where birds or poultry infected with END are located will be designated as a quarantined area, and that a quarantined area is any geographical area, which may be a premises or all or part of a State, deemed by epidemiological evaluation to be

sufficient to contain all birds or poultry known to be infected with or exposed to END. Less than an entire State will be designated as a quarantined area only if the State enforces restrictions on intrastate movements from the quarantined area that are at least as stringent as the regulations. The regulations prohibit or restrict the movement of birds, poultry, products, and materials that could spread END from quarantined areas. Areas quarantined because of END are listed in § 82.3, paragraph (c).

On October 1, 2002, END was confirmed in the State of California. The disease was confirmed in backyard poultry, which are raised on private premises for hobby, exhibition, and personal consumption, and in commercial poultry.

In an interim rule effective on November 21, 2002, and published in the **Federal Register** on November 26, 2002 (67 FR 70674–70675, Docket No. 02–117–1), we amended the regulations in § 82.3(c) by quarantining Los Angeles County, CA, and portions of Riverside and San Bernardino Counties, CA, and restricting the interstate movement of birds, poultry, products, and materials that could spread END from the quarantined area.

In a second interim rule effective on January 7, 2003, and published in the **Federal Register** on January 13, 2003 (68 FR 1515–1517, Docket No. 02–117–2), we further amended § 82.3(c) by adding Imperial, Orange, San Diego, Santa Barbara, and Ventura Counties, CA, and the previously non-quarantined portions of Riverside and San Bernardino Counties, CA, to the list of quarantined areas. Because the Secretary of Agriculture signed a declaration of extraordinary emergency with respect to the END situation in California on January 6, 2003 (*see* 68 FR 1432, Docket No. 03–001–1, published January 10, 2003), that second interim rule also amended the regulations to provide that the prohibitions and restrictions that apply to the interstate movement of birds, poultry, products, and materials that could spread END will also apply to the intrastate movement of those articles in situations where the Secretary of Agriculture has issued a declaration of extraordinary emergency (new § 82.16).

On January 16, 2003, END was confirmed in backyard poultry on a premises in Las Vegas, NV. Therefore, in this interim rule we are amending § 82.3(c) by designating as a quarantined area all of Clark County, NV, and that portion of Nye County, NV, that lies south of U.S. Highway 95 and east of State Highway 373 and by prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. As provided for by the regulations in § 82.3(a), this quarantined area encompasses the area where poultry infected with END were located and a surrounding geographical area deemed by epidemiological evaluation to be sufficient to contain all birds or poultry known to be infected with or exposed to END.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the spread of END. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

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

This rule amends the regulations by quarantining Clark County, NV, and a portion of Nye County, NV, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. This action is necessary on an emergency basis to prevent the spread of END from the quarantined area.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12372

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

Executive Order 12988

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

Paperwork Reduction Act

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

List of Subjects in 9 CFR Part 82

Animal diseases, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 82 is amended as follows:

PART 82—EXOTIC NEWCASTLE DISEASE (END) AND CHLAMYDIOSIS; POULTRY DISEASE CAUSED BY SALMONELLA ENTERITIDIS SEROTYPE ENTERITIDIS

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

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

2. In § 82.3, paragraph (c) is amended by adding, in alphabetical order, an entry for Nevada to read as follows:

§ 82.3 Quarantined areas.

* * * * *

(c) * * *

* * * * *

Nevada

Clark County. The entire county.

Nye County. That portion of the county that lies south of U.S. Highway 95 and east of State Highway 373.

Done in Washington, DC, this 17th day of January 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–1608 Filed 1–23–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–SW–41–AD; Amendment 39–13021; AD 2003–02–05]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, and AS355N Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for certain Eurocopter France (Eurocopter) model helicopters. This action requires measuring the diameter of the sliding door roller (roller) and the dimensions of the front end opening of the sliding door middle rail (rail) to determine if excessive wear exists, and if necessary, installing a placard prohibiting the operation of the sliding door during flight. This amendment is prompted by an incident in which a roller came out of the middle rail during a door-opening operation in flight. The actions specified in this AD are intended to prevent the roller from coming out of the middle rail when opening the door, which could lead to the sliding door separating from the helicopter during flight, damage to critical flight components, and subsequent loss of control of the helicopter.

DATES: Effective February 10, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 10, 2003.

Comments for inclusion in the Rules Docket must be received on or before March 25, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2002-SW–41–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.*

The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Gary Roach, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0111, telephone (817) 222–5130, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: The Direction Generale De L'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on Eurocopter Model AS350 and AS355 helicopters. The DGAC advises that there has been one report of a sliding door aft roller dislodgment in flight due to severe wear on the rail.

Eurocopter has issued Alert Telex No. 05.00.41, applicable to Model AS350 helicopters, and Alert Telex No. 05.00.39, applicable to Model AS355 helicopters, both dated May 16, 2002, which specify measuring the diameter of the sliding door aft roller and rail opening dimension to determine wear, and prohibit operating the door during flight if certain dimensions are exceeded. The DGAC classified these alert telexes as mandatory and issued AD No. 2002–344–093(A), applicable to Model AS350 helicopters, and AD No. 2002–345–070(A), applicable to Model AS355 helicopters, both dated June 26, 2002, to ensure the continued airworthiness of these helicopters in France.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

This unsafe condition is likely to exist or develop on other helicopters of the same type designs registered in the United States. Therefore, this AD is being issued to prevent the roller from coming out of the middle rail when operating the door, which could lead to the sliding door separating from the helicopter during flight and possibly damaging critical flight components, resulting in subsequent loss of control of the helicopter. This AD requires, before further flight and thereafter at intervals not to exceed 100 hours time-in-service, measuring the diameter of the roller and the dimensions of the front end opening of the sliding door rail for wear, and if necessary, installing a placard prohibiting operating the sliding door during flight. The actions must be accomplished in accordance with the alert telexes described previously. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the controllability or structural integrity of the helicopter. Therefore, measuring the diameter of the roller and the dimensions of the rail to determine if excessive wear exists, and if necessary, installing a placard prohibiting the opening of the sliding door during flight is required prior to further flight, and this AD must be issued immediately.

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

The FAA estimates that 50 helicopters will be affected by this AD, that it will take approximately 1 work hour to measure the roller and rail, and 1 work hour to make and apply a placard to the inside door, if necessary, and that the average labor rate is $60 per work hour. Required parts will cost approximately $10 per helicopter if installing a placard is necessary. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $21,500 per year, assuming each helicopter in the fleet is measured 6 times per year, assuming no placards will be necessary.

Comments Invited

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

action and determining whether additional rulemaking action would be needed.

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

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2002–SW–41–AD.'' The postcard will be date stamped and returned to the commenter.

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

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2003–02–05 Eurocopter France: Amendment 39–13021. Docket No. 2002–SW–41–AD.

Applicability: Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters, with sliding door middle rail (middle rail) left upper, part number (P/N) 350A21–1027–36, left lower, P/N 350A21–1027–20, right upper, P/N 350A21–1027–39, right lower, P/N 350A21–1027–21, sliding door roller (roller), P/N 350A25–1274–24, and plate support, P/N 350A21–1335–20, installed, certificated in any category.

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

Compliance: Required before further flight, unless accomplished previously, then at intervals not to exceed 100 hours time-in-service (TIS).

To prevent the roller from coming out of the middle rail when operating the door, which could lead to the sliding door separating from the helicopter during flight, damage to critical flight components, and subsequent loss of control of the helicopter, accomplish the following:

(a) Measure the diameter of the roller and the dimensions of the front end opening of the middle rail in accordance with the Accomplishment Instructions, paragraph 2.B., of Eurocopter Alert Telex No. 05.00.41, applicable to Model AS350 helicopters, and Eurocopter Alert Telex No. 05.00.39, applicable to Model AS355 helicopters, both dated May 16, 2002 (Alert Telexes).

(1) If the rail opening or roller diameter is beyond the permissible limits stated in the Accomplishment Instructions, paragraph 2.B.1., of the Alert Telexes, make a placard that states ''DO NOT OPERATE DOOR IN FLIGHT'' and attach it to the inside of the sliding door. The lettering on the placard must be at least ¼-inch tall and obvious to the crew.

(2) If the sliding door is placarded to prohibit door operation during flight, it is not necessary to measure the roller or rail.

Note 2: Replacing the worn parts does not terminate the requirement to make the measurements required by paragraph (a) of this AD at intervals not to exceed 100 hours TIS.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(c) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the requirements of this AD can be accomplished, so long as the cabin door is not operated during the flight.

(d) The measuring shall be done in accordance with Eurocopter Alert Telex No. 05.00.41, applicable to Model AS350 helicopters, and Eurocopter Alert Telex No. 05.00.39, applicable to Model AS355 helicopters, both dated May 16, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on February 10, 2003.

Note 4: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD No. 2002–344–093(A), applicable to Model AS350 helicopters, and AD No. 2002–345–070(A), applicable to Model AS355 helicopters, both dated June 26, 2002.

Issued in Fort Worth, Texas, on January 11, 2003.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 03–1190 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–SW–33–AD; Amendment 39–13023; AD 2003–02–06]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Model 407 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for Bell Helicopter Textron Canada Limited (Bell) Model 407 helicopters. This action requires visually inspecting certain tailboom gearbox support castings (castings) for cracks and replacing the tailboom assembly if a crack is found. This amendment is prompted by an incident in which a crack was discovered on the casting that holds the tail rotor gearbox and vertical fin. The actions specified in this AD are intended to detect a crack in the casting and prevent failure of the casting, loss of the vertical fin and tail rotor, and subsequent loss of control of the helicopter.

DATES: Effective February 10, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 10, 2003.

Comments for inclusion in the Rules Docket must be received on or before March 25, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2002–SW–33–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9–asw–adcomments@faa.gov.*

The service information referenced in this AD may be obtained from Bell Helicopter Textron Canada, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the **Federal Register,** 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sharon Miles, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5122, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: Transport Canada, the airworthiness authority for Canada, notified the FAA that an unsafe condition may exist on Bell Model 407 helicopters. Transport Canada advises that there has been one occurrence of a cracked tail rotor gearbox support casting that is part of the tailboom assembly. They state that the crack originated from a weld repair made during fabrication of the part and that Bell has identified other castings that have the same repair and potential for cracking.

Bell has issued Bell Helicopter Textron Alert Service Bulletin, No. 407–02–53, dated June 5, 2002, which specifies a procedure for determining if an affected tailboom and casting are installed, and specifies an initial and 25-hour time-in-service recurring visual inspections of the casting for cracks. Transport Canada classified this alert service bulletin as mandatory and issued AD No. CF–2002–32R1, dated July 31, 2002, to ensure the continued airworthiness of these helicopters in Canada.

This helicopter model is manufactured in Canada and is type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, Transport Canada has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

This unsafe condition is likely to exist or develop on other helicopters of the same type design registered in the United States. Therefore, this AD is being issued to detect a crack in the casting and prevent failure of the casting, loss of the vertical fin and tail rotor, and subsequent loss of control of the helicopter. This AD requires determining if an affected tailboom assembly and casting are installed, and if so, visually inspecting the casting for a crack before further flight at intervals not to exceed 25 hours time-in-service (TIS). Replacing any tailboom assembly that has a cracked casting is also required before further flight. The actions must be accomplished in accordance with the alert service bulletin described previously. Replacing the tailboom with a tailboom assembly having a serial number other than those listed in the Applicability section of this AD is a terminating action for the requirements of this AD. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the controllability and structural integrity of the helicopter. Therefore, inspecting for a crack in affected castings is required within 10 hours TIS or 7 days, whichever occurs first, and this AD must be issued immediately.

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

The FAA estimates that 284 helicopters will be affected by this AD and that it will take approximately 1.5 work hours to determine if an affected tailboom assembly and casting are installed and 25 work hours to replace a tailboom. There are seven helicopters that will require repetitively inspecting the affected casting; it will take approximately 1 work hour to conduct the visual inspection of the casting. The average labor rate is $60 per work hour. If a crack is found in the casting, required parts will cost approximately $64,578 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $573,786, assuming (1) a one-time inspection for 284 helicopters to determine if affected tailbooms and castings are installed; and (2) the tailboom is replaced on the seven helicopters after 204 repetitive inspections. The manufacturer states that they are offering a prorated warranty credit for replacement tailboom, P/N 407–030–801–203.

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

evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

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

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2002–SW–33–AD.'' The postcard will be date stamped and returned to the commenter.

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

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

A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2003–02–06 Bell Helicopter Textron Canada Limited: Amendment 39–13023. Docket No. 2002–SW–33–AD.

Applicability: Model 407 helicopters, serial numbers (S/N) 53000 through 53475, with tailboom assemblies, part numbers (P/Ns) 407–030–801–105 or –107, or 407–530–014–103, having S/N 53390 through 53440, 53449, BP921, BP1014, and tail rotor gearbox support casting (casting), part number (P/N) 406–030–121–105, having S/N 980867/01–2, 980867/01–3, 980867/01–4, 980867/01–5, 980867/01–8, 980867/01–9, and 980867/01–10, installed, certificated in any category.

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

Compliance: Required as indicated, unless accomplished previously.

To detect a crack in the casting, failure of the tail rotor, loss of the tailboom, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 10 hours time-in-service (TIS) or 7 days, whichever occurs first, determine if an affected tailboom is installed, and if so, determine if an affected casting is installed, in accordance with Part I of the Accomplishment Instructions in Bell Helicopter Textron Alert Service Bulletin No. 407–02–53, dated June 5, 2002 (ASB), except reporting to the manufacturer is not required.

(b) If an affected tailboom and casting are installed, before further flight and thereafter at intervals not to exceed 25 hours TIS until replacement tailboom, P/N 407–030–801–203, is installed, visually inspect the casting for a crack in accordance with Part II, steps 3–5 and 8, of the Accomplishment Instructions of the ASB, except that reporting to the manufacturer is not required.

(1) If a crack is found, before further flight, replace the tailboom assembly with an airworthy tailboom assembly having a serial number other than those serial-numbered tailboom assemblies listed in the Applicability section of this AD.

(2) If a crack is found, report the following information within 7 days to the FAA, Rotorcraft Directorate, ASW–111, Attention: Sharon Miles, 2601 Meacham Blvd., Fort Worth, TX 76137; or via Email to: *sharon.y.miles@faa.gov;* or via FAX at (817) 222–5961: Tailboom P/N, S/N, number of hours TIS, crack location, and crack size. Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(c) Replacing the tailboom with a tailboom assembly having a serial number other than those listed in the Applicability section of this AD is a terminating action for the requirements of this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

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

(e) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) Determining if affected parts are installed and visually inspecting for a crack shall be done in accordance with Bell Helicopter Textron Alert Service Bulletin, No. 407–02–53, dated June 5, 2002, Part I and Part II, Accomplishment Instructions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bell Helicopter Textron Canada, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on February 10, 2003.

Note 3: The subject of this AD is addressed in Transport Canada (Canada) AD CF–2002–32R1, dated July 31, 2002.

Issued in Fort Worth, Texas, on January 14, 2003.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 03–1304 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T.D. 03–05]

Consolidation of Customs Drawback Centers

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with a clarification, the proposed amendments to the Customs Regulations that reflect the closure of the Customs Drawback Centers located at the ports of Boston, Massachusetts; Miami, Florida; and New Orleans, Louisiana. The closing of the three Drawback Centers is part of a planned consolidation and is intended to promote operational efficiency in the processing of drawback claims.

EFFECTIVE DATES: This regulation becomes effective January 24, 2003. The closing of the Customs Drawback Center located at the port of New Orleans, LA becomes effective February 24, 2003. The closing of the Customs Drawback Centers located at the ports of Boston, MA and Miami, FL become effective July 23, 2003.

FOR FURTHER INFORMATION CONTACT: Sherri Lee Hoffman, Entry and Drawback Management, Office of Field Operations, U.S. Customs Service, Tel. (202) 927–0300.

SUPPLEMENTARY INFORMATION:

Background

Since 1996, Customs has recognized a decrease in both the number of drawback claims and the amount of drawback payments. To verify these trends, and to determine how to most efficiently operate the Drawback Program, Customs conducted an internal evaluation of the program. Customs also retained the services of an independent contractor to review the Drawback Program to ensure that the agency's findings were valid. The findings of both the agency-led review and the independent contractor's assessment indicated the benefits of consolidating the processing of drawback claims by reducing the number of Drawback Centers.

In a Notice to Congress on March 12, 2001, filed in accordance with 19 U.S.C. 2075, Customs proposed the closure of four Drawback Centers. The Senate Finance and House Ways and Means Committees concurred with the proposal for consolidation, but with the recommendation that only three Drawback Centers be eliminated and the San Francisco Drawback Center remain operational. The Commissioner of Customs concurred with this recommendation and it was proposed to phase-in the closure of the Drawback Centers located at the ports of Boston, MA; Miami, FL; and New Orleans, LA.

On August 21, 2002, Customs published in the **Federal Register** (67 FR 54137) a proposed amendment to the Customs Regulations to reflect the planned closure of these Customs Drawback Centers, and a request for public comment regarding the proposed actions. In that document, Customs described a phased-in closure process whereby the Customs Drawback Centers located at the ports of Boston and New Orleans would close 30 days from the date a final rule adopting the proposed changes was published in the **Federal Register**, and the Drawback Center located at the port of Miami would close 180 days from such date. The document also stated that any unliquidated drawback claims that remained at each of these Drawback Centers twelve months after their respective closing dates would be transferred to another Drawback Center for processing as follows: Remaining claims from Boston would be transferred to the New York/Newark, NJ Drawback Center; remaining claims from New Orleans would be transferred to the Houston Drawback Center; and remaining claims from Miami would be transferred to the Chicago Drawback Center.

In accordance with the proposal, the five Drawback Centers located at the ports of New York/Newark, NJ; Houston, TX; Chicago, IL; Los Angeles, CA; and San Francisco, CA, will remain operational.

Discussion of Comments

Fourteen comments were received in response to the solicitation of public comment published in the August 21, 2002, **Federal Register** document. A description of the comments received, together with Customs analyses, is set forth below.

Comment: Several commenters expressed concern that closure of three Drawback Centers will negatively impact the level of service at the remaining Drawback Centers. Specific comments were submitted regarding anticipated inefficiencies at the remaining Drawback Centers resulting from:

- Reduction in full-time Customs Drawback Specialist positions;
- Increased workload for remaining Drawback Specialists and failure to utilize existing Drawback personnel to their potential;
- Transfer of backlogged drawback cases;
- Lack of specific published proposals demonstrating how service levels will be maintained; and
- Lack of realistic methods of determining which Drawback Centers should have been closed;

Customs Response: To ensure that the level of service at the remaining Drawback Centers will remain the same as before the consolidation, Customs reviewed the workload of each Center and assessed the burden of any workload that would be transferred to another Drawback Center as result of the consolidation. The determination as to which Drawback Centers would receive drawback cases that remain unliquidated twelve months after closure of a Center was based upon this review. It is noted, however, that the workload transfers that were described in the August 21, 2002, **Federal Register** document have been changed, due to further internal analysis of workloads, staffing and backlogs, and are described in the section of this document entitled ''Further Customs Analysis,'' set forth below.

Regarding staffing issues, Customs recognizes that Drawback personnel levels at the remaining Drawback Centers will have to be routinely reviewed to ensure that the centers are able to sustain pre-consolidation levels of service. Customs is striving to automate and simplify the drawback process to reduce the workload of Drawback Specialists. In an effort to utilize Drawback personnel to their potential, Drawback Specialists will continue to receive annual training.

The Customs Drawback Program has evolved over the years, and the processing procedures in place today are to ensure that the workload increases do not create unworkable backlogs and preserve a pre-consolidation level of service to the trade.

Lastly, Customs notes that its determination to close three Drawback Centers was based on a detailed internal evaluation of the program, as well as the findings of an independent contractor. The findings of the agency-led review and the independent contractor's assessment were based on facts and clearly indicated the benefits of consolidation of the program.

Comment: Two commenters requested that the requirement to re-apply for a new letter of intent to operate under a general drawback ruling when transferring from one drawback center to another be waived.

Customs response: Claimants will not have to re-file a general drawback ruling request at the Drawback Center designated to receive their claims. If, however, a claimant opts to file a claim at a Drawback Center other than the one designated to receive their claims, that claimant will have to file a new letter of intent to operate under a general drawback ruling at that location.

Comment: Several commenters questioned whether consolidating the drawback program would subvert the intent of Congress to assist in increasing U.S. exports.

Customs response: Consolidation of the drawback program will not negatively impact U.S. exports.

Comment: One commenter objected to the fact that the identity of the independent contractor brought in to perform the review of the Drawback Program was not made public.

Customs response: The purpose of retaining an independent contractor was to have an unbiased third party conduct a review of the Drawback Program. Individuals seeking more information may file a request for information pursuant to the Freedom of Information Act (5 U.S.C. 552).

Comment: Several commenters noted that although the number of drawback claims has decreased, the volume of import and export shipments that appear on claims has increased.

Customs response: Customs has data that reflects that the number of underlying imports in 2001 decreased over 40% from 1999 levels. While it is true that more exports are being claimed in a summarized format, consolidation of the drawback program is a legitimate means of increasing the program's efficiency without impairing U.S. exports.

Comment: Two commenters questioned why claimants are not allowed to file a single application for the waivers and privileges set forth in §§ 191.91, 191.92 and 191.195 of the Customs Regulations (*i.e.*, waiver of prior notice of intent to export, accelerated payment, certification in the drawback compliance program).

Customs response: Claimants do have the option of filing a single application for these waivers and privileges pursuant to 19 CFR 191.93.

Comment: Several commenters noted that all Drawback Specialists must now perform more mandatory audits and/or desk reviews as ordered by the General Accounting Office (GAO).

Customs response: Customs has enhanced the processing procedures for drawback so that fewer full desk reviews are completed by each Drawback Specialist. Audits are completed by Regulatory Auditors with input from the Drawback Specialist. It is noted that the number of audits over the years has remained consistent.

Comment: One commenter noted that the proposed rulemaking should have stated that only a customs broker requires a license/permit to file a drawback claim, and not a drawback claimant.

Customs response: Customs agrees; the background section of the proposed rulemaking published in the **Federal Register** (67 FR 54137) on August 21, 2002, should have specified that a drawback claimant's customs broker must possess a district or national permit to file a drawback claim.

Comment: One commenter questioned whether a broker must file drawback claims via the Automated Broker Interface (ABI) to have a national permit, and noted that the Customs Regulations permit drawback claims to be filed either manually or electronically (via ABI).

Customs response: Section 111.19(f) of the Customs Regulations (19 CFR 111.19(f)) allows for national broker permits under any of the circumstances described in § 111.2(b)(2)(i) (19 CFR 111.2(b)(2)(i)). Section 111.2(b)(2)(i)(B) allows for electronic (ABI) drawback claims. There is no allowance in § 111.2(b)(2)(i) for manual drawback claims. Drawback claims may be filed manually by brokers with a district permit. *See* 19 CFR 111.2(b)(2)(ii).

Comment: Several commenters noted that by closing Drawback Centers, Customs will be unable to liquidate and audit drawback claims within the three year time period allowed by law.

Customs response: As stated previously, Customs believes that consolidation of the Drawback Program will bring about more efficient and effective drawback claim processing, and thereby claims should get liquidated more expeditiously. It is noted that there is no legal or regulatory requirement to liquidate or audit a drawback claim within three years. A drawback claimant is required to retain records for three years after payment of a drawback claim. *See* 19 CFR 163.4(b)(1). If drawback is paid via accelerated payment, pursuant to 19 CFR 191.92, and the three year time period to retain records expires prior to the underlying claim being liquidated, there may be instances where the records necessary to verify a claim are no longer available. This problem, however, has no bearing on the consolidation of the Drawback Program. It is further noted that audits are performed on unliquidated drawback claims, and this document does not make any changes to the Regulatory Audit functions of drawback.

Comment: One commenter viewed the requirement to provide advance notification to Customs of any changes to a drawback claim as impractical, and questioned who, within Customs, should be notified in such instances.

Customs response: Notification of changes to a drawback claim should be provided to the Drawback Specialist handling the original claim.

Comment: One commenter questioned whether the Government will actually save money by closing three Drawback Centers and reducing personnel, given the fact that no specific information as to the expected savings have been presented.

Customs response: The proposed rulemaking published in the August 21, 2002, **Federal Register** stated that the consolidation is ''intended to promote operational efficiency in the processing of drawback claims.'' The document does not suggest savings as a reason for the consolidation.

Comment: One commenter noted that consolidation of the Drawback Program will necessitate submission of drawback applications to Customs Drawback Centers that are outside the Customs port areas most familiar with the claimant/company and thereby further increase delays and backlogs. Additionally, if drawback claims are required to be submitted at ports other than the port of import, the process of obtaining records will be more difficult, time-consuming and expensive.

Customs response: The Drawback Program is not currently a port-specific program. Therefore, Drawback Specialists are already adept at reviewing claims that originate from outside their geographical area. Also, the process of transmitting or shipping data to other Customs ports is already followed by all ports that do not have a Drawback Center.

Comment: One commenter requested that Customs publish each Drawback Center's drawback claims filing statistics (*i.e.*, dollar amounts claimed, number of drawback personnel assigned to the Drawback Center, number of exports being claimed).

Customs response: Relevant export data is unavailable because it is not part of Customs automated system. The other types of drawback statistics specified in the comment may be available by information requests made pursuant to the Freedom of Information Act (5 U.S.C. 552).

Comment: One commenter noted that a decline in the number of drawback claims suggests that existing Drawback Centers have idle time and that

privileges and claims should all be approved on time, including those applications made at Customs Headquarters.

Customs response: Applications for privileges are not approved at Customs Headquarters. Customs is being proactive, rather than reactive, by consolidating the Drawback Program and ensuring that Drawback resources are used optimally.

Comment: One commenter stated that Customs will increase costs by closing some of the Drawback Centers because a Drawback Specialist usually visits the drawback claimant with an Auditor and this will increase Customs travel expenses. In a related comment, several commenters noted that by closing the Boston Drawback Center, Customs expenses will increase because Auditors and Inspectors will have to travel to remote customs sites beyond their port's geographical area to review and audit drawback claims.

Customs response: A Drawback Specialist does not always accompany an Auditor. Moreover, Drawback Specialists are technical experts that an Auditor can consult as a resource either electronically or telephonically. Customs already incurs some of these travel expenditures in that a drawback claimant can use any of the eight existing Drawback Centers and does not always choose to file a drawback claim at the Center located nearest the claimant. Regarding the comment directed at the Boston Drawback Center, it is noted that Auditors and Inspectors are located throughout the Customs Service. Regulatory Auditors will remain in Boston, as well as other sites. Inspectors located at the port of export will perform the export examinations, as they always have. They perform functions separate from those of a Drawback Specialist and the role of Inspectors will not be affected by the consolidation.

Comment: Several commenters stated that the cost of staffing and training new Drawback personnel will be significant.

Customs response: The remaining Drawback Centers have well-trained, capable staffs and there is no need to immediately increase staffing levels at those Centers. New staff will be hired to replace personnel lost through attrition or retirement and to accommodate any sustained increase in drawback filings nationwide.

Comment: Several commenters noted that as proposed Free Trade Agreements and yearly reductions in duty rates will eventually eliminate the need for drawback, closure of the Drawback Centers at this time is unwarranted.

Customs response: Customs views a consolidated, more efficient Drawback Program as consistent with the trade trends cited in the comment above.

Comment: Several commenters are of the view that it is not prudent to change the Drawback Program during this time of transition of the Customs Service to the Homeland Security Department and that any such changes will distract from the goals of fighting terrorism.

Customs response: Customs is of the view that the agency's efforts regarding anti-terrorism and its move to the Homeland Security Department will not be impacted by any of the changes to the Drawback Program discussed in this document.

Comment: Several commenters questioned why California will have two Drawback Centers operating after the consolidation, even though Boston has more volume than the Los Angeles Drawback Center. The commenters also suggested documenting the length of time it takes certain Drawback Centers to process drawback claims and correcting inefficiencies.

Customs response: As stated above, many factors were taken into consideration in making the determination to close the Boston Drawback Center. Regarding workload volume, Customs notes that the volume at the Boston and Los Angeles Centers is approximately the same.

Comment: Several commenters stated that exporters will have their costs increased by having to submit drawback applications and claims to remote Drawback Centers. The commenters also expected increased delays in having to wait for shipment inspections and payment of drawback claims.

Customs response: Exporters file their claims at the port of exportation. A Drawback Center has no bearing on the export process. There is no reason to believe there will be any delays in shipment inspections, as there have been no changes made to this process.

Further Customs Analysis

Customs has determined that based on the above comments, no change is necessary to the proposed rulemaking published in the **Federal Register** on August 21, 2002 (67 FR 54137). However, it has come to Customs attention, upon further review of the proposed consolidation, that a redistribution of the workload that is to be transferred from the closed Drawback Centers, as well as an extension of the time period that the Boston Drawback Center will remain operational, will assist in maintaining the level of service at the remaining Drawback Centers that existed prior to consolidation.

The original phased-in consolidation plan, which detailed the transfer of remaining unliquidated drawback cases and the time frames for Drawback Center closures, as published in the August 21, 2002, **Federal Register** document, remains in effect except for the following changes:

(1) Drawback claims that remain unliquidated twelve months after closure of the Miami Drawback Center and require Customs review will be forwarded to the Los Angeles Drawback Center (not to the Chicago Drawback Center); and

(2) The Drawback Center at the port of Boston, MA will close 180 days from the date of publication of this document in the **Federal Register** (not 30 days from such date as originally planned). As of that date, drawback claims will no longer be accepted at the Boston Drawback Center and claims must be filed at one of the five remaining Drawback Centers. Drawback claims submitted to the Boston Drawback Center after this date will be rejected. Once rejected, it is the responsibility of the claimant to ensure timely filing of the drawback claim at one of the five remaining Drawback Centers. Customs personnel at the port of Boston will continue to process drawback claims for a period of 12-months after closure of the Boston Drawback Center. After this time, all remaining unliquidated drawback claims filed at the Boston Drawback Center prior to its closure that require Customs review will be forwarded to the Chicago Drawback Center for final processing (not to the New York/Newark Drawback Center as originally planned).

Conclusion

After analysis of the comments and further review of the matter, Customs has determined to adopt as a final rule the amendments proposed in the Notice of Proposed Rulemaking published in the **Federal Register** (67 FR 54137) on August 21, 2002.

Inapplicability of Delayed Effective Date

Although this final rule was issued after a notice for public comments, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553 because it relates to agency management and organization. Customs solicited and reviewed comments as a courtesy to the public. Accordingly, there is no requirement for a delayed effective date for this regulation.

The Regulatory Flexibility Act and Executive Order 12866

Because these amendments relate to agency management and organization, they are not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Agency organization matters, such as this proposed closing of three Customs Drawback Centers, are not subject to Executive Order 12866.

Drafting Information

The principal author of this document was Ms. Suzanne Kingsbury, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Customs ports of entry.

Amendments to the Regulations

For the reasons set forth in the preamble, amend part 101 of the Customs Regulations (19 CFR 101) as follows:

PART 101—GENERAL PROVISIONS

1. The general authority citation for part 101 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

Section 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

§ 101.3 [Amended]

2. In § 101.3, the table in paragraph (b)(1) is amended by removing the plus sign in the ''Ports of entry'' column before the column listings for ''Miami'' under the state of Florida, ''New Orleans'' under the state of Louisiana, and ''Boston'' under the state of Massachusetts.

Robert C. Bonner,

Commissioner of Customs.

Approved: January 22, 2003.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 03–1758 Filed 1–23–03; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9038]

RIN 1545–BB46

Statutory Mergers and Consolidations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations that define the term *statutory merger or consolidation* as that term is used in section 368(a)(1)(A). These regulations affect corporations engaging in statutory mergers and consolidations, and their shareholders. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the proposed rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Richard M. Heinecke or Reginald Mombrun at (202) 622–7930 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

A. Section 368(a) Generally

The Internal Revenue Code of 1986 (Code) provides general nonrecognition treatment for reorganizations specifically described in section 368(a). Section 368(a)(1)(A) provides that the term *reorganization* includes ''a statutory merger or consolidation.'' Section 1.368–2(b)(1) currently provides that a statutory merger or consolidation must be ''effected pursuant to the corporation laws of the United States or a State or Territory or the District of Columbia.''

B. Disregarded Entities Generally

A business entity (as defined in § 301.7701–2(a)) that has only one owner may be disregarded as an entity separate from its owner for Federal tax purposes. Examples of disregarded entities include a domestic single member limited liability company that does not elect to be classified as a corporation for Federal tax purposes, a corporation (as defined in § 301.7701–2(b)) that is a qualified REIT subsidiary (within the meaning of section 856(i)(2)) (hereinafter referred to as ''QRS''), and a corporation that is a qualified subchapter S subsidiary (within the meaning of section 1361(b)(3)(B)) (hereinafter sometimes referred to as ''QSub'').

Because a QRS and QSub are corporations under state law, state merger laws generally permit them to merge with other corporations. In addition, many state merger laws permit a limited liability company (LLC) to merge with another LLC or with a corporation.

C. Previous Proposals of Regulations

On May 16, 2000, the IRS and Treasury issued a notice of proposed rulemaking (REG–106186–98; 65 FR 31115) (hereinafter referred to as the 2000 proposed regulations) providing that neither the merger of a disregarded entity into a corporation nor the merger of a corporation into a disregarded entity would qualify as a reorganization under section 368(a)(1)(A). While commentators generally agreed that the merger of a disregarded entity into a corporation should not qualify as a reorganization under section 368(a)(1)(A), commentators asserted that the merger of a corporation into a disregarded entity with a corporate owner should be able to qualify as a reorganization under section 368(a)(1)(A).

On November 15, 2001, after consideration of the comments received regarding the 2000 proposed regulations, the IRS and Treasury withdrew the 2000 proposed regulations (REG–106186–98; 66 FR 57400) and issued another notice of proposed rulemaking (REG–126485–01; 66 FR 57400) (hereinafter referred to as the 2001 proposed regulations).

The 2001 proposed regulations provide that, for purposes of section 368(a)(1)(A), a statutory merger or consolidation must be effected pursuant to the laws of the United States or a State or the District of Columbia. Pursuant to such laws, the following events must occur simultaneously at the effective time of the transaction: (1) All of the assets (other than those distributed in the transaction) and liabilities (except to the extent satisfied or discharged in the transaction) of each member of one or more combining units (each a transferor unit) become the assets and liabilities of one or more members of one other combining unit (the transferee unit); and (2) the combining entity of each transferor unit ceases its separate legal existence for all purposes. For this purpose, a combining entity is a business entity that is a corporation (as defined in § 301.7701–2(b)) that is not a disregarded entity)

and a combining unit is a combining entity and all of its disregarded entities.

The 2001 proposed regulations provide that the merger of a disregarded entity into a corporation will not qualify as a statutory merger or consolidation under section 368(a)(1)(A) because all of the transferor unit's assets may not be transferred to the transferee unit and the separate legal existence of the combining entity of the transferor unit does not terminate as a matter of law. The 2001 proposed regulations, however, generally provide that the merger of a corporation into a disregarded entity will qualify as a statutory merger or consolidation if it satisfies the requirements of the regulations.

No public hearing regarding the 2001 proposed regulations was requested or held. Nonetheless, a number of written comments were received.

Explanation of Provisions

The IRS and Treasury have studied the comments received regarding the 2001 proposed regulations. Although the IRS and Treasury are continuing to study a number of the comments received regarding the proposed regulations, in response to a number of comments requesting immediate guidance in this area upon which taxpayers may rely, the IRS and Treasury are promulgating these regulations as temporary regulations in this Treasury Decision. The temporary regulations retain the general framework of the 2001 proposed regulations, but make certain modifications in response to comments received. The following sections describe a number of the most significant comments and the extent to which they have been incorporated in these temporary regulations. Further changes to the temporary regulations, however, are possible before these regulations are finalized.

A. Definition of Combining Entity

As described above, the 2001 proposed regulations define a combining entity as a business entity that is a corporation that is not a disregarded entity. Although the preamble to the 2001 proposed regulations clarifies that, for this purpose, the term corporation is defined as provided in § 301.7701–2(b), commentators requested that that clarification also be provided in the text of the regulations. In response to these comments, the temporary regulations provide that a combining entity is a corporation (as defined in § 301.7701–2(b)) that is not a disregarded entity.

B. The All of the Assets Requirement

As stated above, the 2001 proposed regulations require that all of the assets of a transferor unit become the assets of a transferee unit. A number of comments were received regarding this requirement. The following paragraphs describe these comments and the extent to which the temporary regulations reflect them.

One comment suggested that the regulations be amended to clarify that whether the all of the assets requirement is satisfied is determined by reference to the assets of the transferor unit immediately prior to the merger. These temporary regulations add an example that illustrates that a transaction that is preceded by a distribution by the transferor unit to its shareholders may qualify as a statutory merger under these temporary regulations, even if the ''substantially all'' requirement applicable to certain other types of reorganizations would not be satisfied. The example is provided solely to illustrate the meaning of the all of the assets requirement. No inference is intended regarding the shareholder level and other tax consequences of the transaction described therein.

Another comment stated that the proposed regulations are unclear as to whether a transaction in which an entity that is disregarded as an entity separate from the combining entity of the transferor unit becomes an entity that is disregarded as an entity separate from the combining entity of the transferee unit satisfies the all of the assets requirement. These temporary regulations amend *Example 2* of the 2001 proposed regulations, as described below, to clarify that this transaction may satisfy the all of the assets requirement and, therefore, qualify as a statutory merger or consolidation.

C. The Cessation of Separate Legal Existence Requirement

The 2001 proposed regulations require that the combining entity of each transferor unit ''ceases its separate legal existence for all purposes.'' One comment requested that the phrase ''for all purposes'' be deleted from this requirement. The comment suggested that under some corporate laws a merged corporation may continue its existence for a specified time period and for certain limited purposes, such as bringing and defending against lawsuits. This limited continued existence of a combining entity of a transferor unit, the comment suggested, should not prevent a transaction from being treated as failing to satisfy the requirement that the combining entity of each transferor unit cease its separate legal existence for all purposes.

The IRS and Treasury do not believe that the deletion of ''for all purposes'' from the regulation will alter the terms of the requirement. Nonetheless, these temporary regulations provide that this requirement will be satisfied even if, pursuant to the laws of the United States or a State or the District of Columbia, after the effective time of the transaction, the combining entity of the transferor unit (or its officers, directors, or agents) may act or be acted against, or a member of the transferee unit (or its officers, directors, or agents) may act or be acted against in the name of the combining entity of the transferor unit, provided that such actions relate to assets or obligations of the combining entity of the transferor unit that arose, or relate to activities engaged in by such entity, prior to the effective time of the transaction, and such actions are not inconsistent with the all of the assets requirement.

D. Example 2 of the 2001 Proposed Regulations

A number of comments were received regarding *Example 2* of the 2001 proposed regulations, which involves the merger of a target corporation into a disregarded entity. The last sentence of the facts of *Example 2* states that, ''[p]rior to the transaction, [the combining entity of the transferor unit] is not treated as owning any assets of an entity that is disregarded as an entity separate from its owner for Federal tax purposes.'' One commentator indicated that it is not clear why this fact is relevant to the conclusion that the transaction qualifies as a statutory merger or consolidation and suggested either deleting or clarifying this fact.

As described above, in order to qualify as a statutory merger or consolidation, all of the assets of a transferor unit must become assets of the transferee unit. In order to determine whether this requirement has been satisfied, it is necessary to know whether the combining entity of the transferor unit owns the interests of any entity that is disregarded as an entity separate from its owner for Federal tax purposes. The last sentence of the facts of *Example 2* was merely intended to convey the fact that the only assets of the transferor unit were those that the combining entity owned directly. To clarify the significance of this fact, the temporary regulations amend the analysis in *Example 2* to indicate that the transaction would still qualify as a statutory merger or consolidation even if the combining entity of the transferor unit were treated as owning assets of an

entity that is disregarded as an entity separate from the combining entity of the transferor unit for Federal tax purposes, provided that those assets become assets of the transferee unit.

E. Additional Examples

One commentator suggested that the scope of the proposed regulations be clarified through additional examples. The following paragraphs describe the suggested examples and the extent to which they have been incorporated in these temporary regulations.

1. QSub That Becomes a C Corporation

A QSub may cease to be a disregarded entity because of an event that renders the subsidiary ineligible for QSub status, such as a merger into an entity owned by a C corporation. For example, suppose Z, an S corporation, owns all of the stock of B, a QSub, and Z merges with and into X, an entity that is disregarded as an entity separate from Y, a C corporation. B's status as a QSub will terminate at the end of the day on which the merger occurs. *See* Treas. Reg. § 1.1361–5(a)(1)(iii). A commentator suggested that, in this case, it is not clear whether B is a member of the transferor unit. If B were treated as a member of the transferor unit, the transaction may not qualify as a statutory merger or consolidation because the assets of B may not become assets of the transferee unit. If, however, B were not treated as a member of the transferor unit, the transaction may qualify as a statutory merger or consolidation. The commentator suggested that B should not be treated as a member of the transferor unit. Alternatively, the commentator suggested that the principles of *Example 9* of § 1.1361–5(b)(3) could be applied to this case. In *Example 9* of § 1.1361–5(b)(3), the acquisition of the stock of a QSub is treated as a transfer of the QSub's assets followed by the transfer of those assets by the acquirer to a new corporation.

The IRS and Treasury agree with the commentator that the principles illustrated by *Example 9* of § 1.1361–5(b)(3) apply to determine whether the merger of Z into X qualifies as a statutory merger or consolidation. In particular, the transaction should be treated as a transfer of B's assets to X followed by a transfer of such assets by X to a new corporation. Accordingly, the transaction may qualify as a statutory merger or consolidation provided that the other requirements of a statutory merger or consolidation are satisfied. These temporary regulations include an example illustrating this result.

2. Transitory Surviving Disregarded Entity

One commentator suggested that the 2001 proposed regulations be amended to provide an example in which the surviving disregarded entity in an otherwise qualifying statutory merger or consolidation is transitory. For example, suppose corporation Z merges into X, an entity that is disregarded as separate from corporation Y. In the transaction, the shareholders of Z exchange their Z stock for Y stock. Immediately after the merger of Z into X and as part of a plan that includes that merger, X merges into Y. The commentator noted that, in Rev. Rul. 72–405 (1972–2 C.B. 217), the IRS held that a forward triangular merger of a target corporation into a newly formed controlled corporation of a parent corporation followed by the liquidation of the controlled corporation into the parent corporation would be treated as a reorganization under section 368(a)(1)(C) rather than a reorganization under sections 368(a)(1)(A) and 368(a)(2)(D). The commentator suggested that the principles of Revenue Ruling 72–405 should not be applied to prevent the merger of Z into X from qualifying as a reorganization under section 368(a)(1)(A).

The IRS and Treasury agree that the merger of Z into X followed by the merger of X into Y does not implicate the principles of Revenue Ruling 72–405. Because the merger of X into Y does not alter the identity of the tax owner of the former assets of X, that merger would be disregarded. The IRS and Treasury do not believe that an additional example is necessary to illustrate this result.

F. The Domestic Entity Requirement

The 2001 proposed regulations provide that a transaction in which any of the assets and liabilities of a combining entity of a transferor unit become assets and liabilities of one or more disregarded entities of the transferee unit cannot qualify as a statutory merger or consolidation unless such combining entity, the combining entity of the transferee unit, such disregarded entities, and each business entity through which the combining entity of the transferee unit holds its interests in such disregarded entities is organized under the laws of the United States or a State or the District of Columbia. One commentator suggested that where an entity that is disregarded as an entity separate from the combining entity of the transferor unit becomes an entity that is disregarded as an entity separate from the combining entity of the transferee unit, whether such disregarded entity is organized under the laws of the United States or a State or the District of Columbia is not relevant to whether the transaction qualifies as a statutory merger or consolidation. The IRS and Treasury agree and have clarified the domestic entity requirement to exclude such disregarded entities.

Another comment suggested that the domestic entity requirement be eliminated for the disregarded entity into which a target corporation is merged and each business entity through which the combining entity holds its interests in the disregarded entity into which a target corporation is merged. Although these temporary regulations retain that requirement for those entities, as described in the preamble to the 2001 proposed regulations, the IRS and Treasury are continuing to consider further revisions to the regulations under section 368(a)(1)(A) to address statutory mergers and consolidations that involve one or more foreign corporations, including transactions involving a disregarded entity.

Special Analyses

It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these temporary regulations is Richard M. Heinecke, Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and record keeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. In § 1.368–2, paragraph (b)(1) is revised to read as follows:

§ 1.368–2 Definition of terms.

* * * * *

(b)(1) For rules regarding statutory mergers or consolidations on or after January 24, 2003, *see* § 1.368–2T(b)(1). For rules regarding statutory mergers or consolidations before January 24, 2003, *see* § 1.368–2(b)(1) as in effect before January 24, 2003 (*see* 26 CFR part 1, revised April 1, 2002).

* * * * *

Par. 3. Section 1.368–2T is added to read as follows:

§ 1.368–2T Definition of terms (temporary).

(a) [Reserved]. For further guidance, *see* § 1.368–2(a).

(b)(1)(i) *Definitions.* For purposes of this paragraph (b)(1), the following terms shall have the following meanings:

(A) *Disregarded entity.* A disregarded entity is a business entity (as defined in § 301.7701–2(a) of this chapter) that is disregarded as an entity separate from its owner for Federal tax purposes. Examples of disregarded entities include a domestic single member limited liability company that does not elect to be classified as a corporation for Federal tax purposes, a corporation (as defined in § 301.7701–2(b) of this chapter) that is a qualified REIT subsidiary (within the meaning of section 856(i)(2)), and a corporation that is a qualified subchapter S subsidiary (within the meaning of section 1361(b)(3)(B)).

(B) *Combining entity.* A combining entity is a business entity that is a corporation (as defined in § 301.7701–2(b) of this chapter) that is not a disregarded entity.

(C) *Combining unit.* A combining unit is composed solely of a combining entity and all disregarded entities, if any, the assets of which are treated as owned by such combining entity for Federal tax purposes.

(ii) *Statutory merger or consolidation generally.* For purposes of section 368(a)(1)(A), a statutory merger or consolidation is a transaction effected pursuant to the laws of the United States or a State or the District of Columbia, in which, as a result of the operation of such laws, the following events occur simultaneously at the effective time of the transaction—

(A) All of the assets (other than those distributed in the transaction) and liabilities (except to the extent satisfied or discharged in the transaction) of each member of one or more combining units (each a transferor unit) become the assets and liabilities of one or more members of one other combining unit (the transferee unit); and

(B) The combining entity of each transferor unit ceases its separate legal existence for all purposes; provided, however, that this requirement will be satisfied even if, pursuant to the laws of the United States or a State or the District of Columbia, after the effective time of the transaction, the combining entity of the transferor unit (or its officers, directors, or agents) may act or be acted against, or a member of the transferee unit (or its officers, directors, or agents) may act or be acted against in the name of the combining entity of the transferor unit, provided that such actions relate to assets or obligations of the combining entity of the transferor unit that arose, or relate to activities engaged in by such entity, prior to the effective time of the transaction, and such actions are not inconsistent with the requirements of paragraph (b)(1)(ii)(A) of this section.

(iii) *Statutory merger or consolidation involving disregarded entities.* A transaction effected pursuant to the laws of the United States or a State or the District of Columbia in which any of the assets and liabilities of a combining entity of a transferor unit become assets and liabilities of one or more disregarded entities of the transferee unit is not a statutory merger or consolidation within the meaning of section 368(a)(1)(A) and paragraph (b)(1)(ii) of this section unless such combining entity, the combining entity of the transferee unit, such disregarded entities other than entities that were disregarded entities of the transferor unit immediately prior to the transaction, and each business entity through which the combining entity of the transferee unit holds its interests in such disregarded entities is organized under the laws of the United States or a State or the District of Columbia.

(iv) *Examples.* The following examples illustrate the rules of paragraph (b)(1) of this section. In each of the examples, except as otherwise provided, each of V, Y, and Z is a domestic C corporation. X is a domestic limited liability company. Except as otherwise provided, X is wholly owned by Y and is disregarded as an entity separate from Y for Federal tax purposes. The examples are as follows:

Example 1. Divisive transaction pursuant to a merger statute. (i) Under State W law, Z transfers some of its assets and liabilities to Y, retains the remainder of its assets and liabilities, and remains in existence following the transaction. The transaction qualifies as a merger under State W corporate law. Prior to the transaction, Y is not treated as owning any assets of an entity that is disregarded as an entity separate from its owner for Federal tax purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because all of the assets and liabilities of Z, the combining entity of the transferor unit, do not become the assets and liabilities of Y, the combining entity and sole member of the transferee unit. In addition, the transaction does not satisfy the requirements of paragraph (b)(1)(ii)(B) of this section because the separate legal existence of Z does not cease for all purposes. Accordingly, the transaction does not qualify as a statutory merger or consolidation under section 368(a)(1)(A).

Example 2. Merger of a target corporation into a disregarded entity in exchange for stock of the owner. (i) Under State W law, Z merges into X. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z become the assets and liabilities of X and Z's separate legal existence ceases for all purposes. In the merger, the Z shareholders exchange their stock of Z for stock of Y. Prior to the transaction, Z is not treated as owning any assets of an entity that is disregarded as an entity separate from its owner for Federal tax purposes.

(ii) The transaction satisfies the requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, become the assets and liabilities of one or more members of the transferee unit that is comprised of Y, the combining entity of the transferee unit, and X, a disregarded entity the assets of which Y is treated as owning for Federal tax purposes, and Z ceases its separate legal existence for all purposes. Paragraph (b)(1)(iii) of this section does not apply to prevent the transaction from qualifying as a statutory merger or consolidation for purposes of section 368(a)(1)(A) because each of Z, Y, and X is a domestic entity. Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A). The result would be the same if Z were treated as owning assets of an entity that is disregarded as an entity separate from Z, regardless of whether such disregarded entity became an entity disregarded as an entity separate from Y as a result of the transaction, or merged into X or a domestic entity disregarded as an entity separate from Y.

Example 3. Merger of a target S corporation that owns a QSub into a disregarded entity. (i) The facts are the same as in *Example 2,* except that Z is an S corporation and owns all of the stock of U, a QSub.

(ii) The deemed formation by Z of U pursuant to § 1.1361–5(b)(1) (as a consequence of the termination of U's QSub election) is disregarded for Federal income tax purposes. The transaction is treated as a transfer of the assets of U to X, followed by X's transfer of these assets to U in exchange for stock of U. *See* § 1.1361–5(b)(3), *Example 9.* The transaction will, therefore, satisfy the

requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z and U, the sole members of the transferor unit, become the assets and liabilities of one or more members of the transferee unit that is comprised of Y, the combining entity of the transferee unit, and X, a disregarded entity the assets of which Y is treated as owning for Federal tax purposes, and Z ceases its separate legal existence for all purposes. Paragraph (b)(1)(iii) of this section does not apply to prevent the transaction from qualifying as a statutory merger or consolidation for purposes of section 368(a)(1)(A) because each of Z, Y, and X is a domestic entity. Moreover, the deemed transfer of the assets of U in exchange for U stock does not cause the transaction to fail to qualify as a statutory merger or consolidation. *See* § 368(a)(2)(C). Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 4. Triangular merger of a target corporation into a disregarded entity. (i) The facts are the same as in *Example 2,* except that V owns 100 percent of the outstanding stock of Y and, in the merger of Z into X, the Z shareholders exchange their stock of Z for stock of V. In the transaction, Z transfers substantially all of its properties to X.

(ii) The transaction is not prevented from qualifying as a statutory merger or consolidation under section 368(a)(1)(A), provided the requirements of section 368(a)(2)(D) are satisfied. Because the assets of X are treated for Federal tax purposes as the assets of Y, Y will be treated as acquiring substantially all of the properties of Z in the merger for purposes of determining whether the merger satisfies the requirements of section 368(a)(2)(D). As a result, the Z shareholders that receive stock of V will be treated as receiving stock of a corporation that is in control of Y, the combining entity of the transferee unit that is the acquiring corporation for purposes of section 368(a)(2)(D). Accordingly, the merger will satisfy the requirements of section 368(a)(2)(D).

Example 5. Merger of a target corporation into a disregarded entity owned by a partnership. (i) The facts are the same as in *Example 2,* except that Y is organized as a partnership under the laws of State W and is classified as a partnership for Federal tax purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section. All of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, do not become the assets and liabilities of one or more members of a transferee unit because neither X nor Y qualifies as a combining entity. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 6. Merger of a disregarded entity into a corporation. (i) Under State W law, X merges into Z. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of X (but not the assets and liabilities of Y other than those of X) become the assets and liabilities of Z and X's separate legal existence ceases for all purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because all of the assets and liabilities of a transferor unit do not become the assets and liabilities of one or more members of the transferee unit. The transaction also does not satisfy the requirements of paragraph (b)(1)(ii)(B) of this section because X does not qualify as a combining entity. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 7. Merger of a corporation into a disregarded entity in exchange for interests in the disregarded entity. (i) Under State W law, Z merges into X. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z become the assets and liabilities of X and Z's separate legal existence ceases for all purposes. In the merger of Z into X, the Z shareholders exchange their stock of Z for interests in X so that, immediately after the merger, X is not disregarded as an entity separate from Y for Federal tax purposes. Following the merger, pursuant to § 301.7701–3(b)(1)(i) of this chapter, X is classified as a partnership for Federal tax purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because immediately after the merger X is not disregarded as an entity separate from Y and, consequently, all of the assets and liabilities of Z, the combining entity of the transferor unit, do not become the assets and liabilities of one or more members of a transferee unit. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 8. Merger transaction preceded by distribution. (i) Z operates two unrelated businesses, Business P and Business Q, each of which represents 50 percent of the value of the assets of Z. Y desires to acquire and continue operating Business P, but does not want to acquire Business Q. Pursuant to a single plan, Z sells Business Q for cash to parties unrelated to Z and Y in a taxable transaction, and then distributes the proceeds of the sale pro rata to its shareholders. Then, pursuant to State W law, Z merges into Y. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z related to Business P become the assets and liabilities of Y and Z's separate legal existence ceases for all purposes. In the merger, the Z shareholders exchange their Z stock for Y stock. Prior to the transaction, Z is not treated as owning any assets of an entity that is disregarded as an entity separate from its owner for Federal tax purposes.

(ii) The transaction satisfies the requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the following events occur simultaneously at the effective time of the transaction: all of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, become the assets and liabilities of Y, the combining entity and sole member of the transferee unit, and Z ceases its separate legal existence for all purposes. Paragraph (b)(1)(iii) of this section does not apply to prevent the transaction from qualifying as a statutory merger or consolidation for purposes of section 368(a)(1)(A) because each of Z and Y is a domestic entity. Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

(v) *Effective dates.* This paragraph (b)(1) applies to transactions occurring on or after January 24, 2003. Taxpayers, however, may apply these regulations in whole, but not in part, to transactions occurring before January 24, 2003, provided that, if the taxpayer is the acquiring corporation (or a shareholder of the acquiring corporation whose tax treatment of the transaction reflects the tax treatment by the acquiring corporation, such as a shareholder of an acquiring S corporation), the target corporation (and the shareholders of the target corporation whose tax treatment of the transaction reflects the tax treatment by the target corporation) also applies these regulations in whole, but not in part, to the transaction, and if the taxpayer is the target corporation (or a shareholder of the target corporation whose tax treatment of the transaction reflects the tax treatment by the target corporation), the acquiring corporation (and the shareholders of the acquiring corporation whose tax treatment of the transaction reflects the tax treatment by the acquiring corporation) also applies these regulations in whole, but not in part, to the transaction. For all other transactions, *see* § 1.368–2(b)(1) as in effect before January 24, 2003 (*see* 26 CFR part 1, revised April 1, 2002).

(b)(2) through (k) [Reserved]. For further guidance, *see* § 1.368–2(b)(2) through (k).

David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

Approved: January 17, 2003.

Pamela F. Olson,

Assistant Secretary of the Treasury.

[FR Doc. 03–1544 Filed 1–23–03; 8:45 am]

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DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the District of Columbia Code

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is amending its rules which govern the hearing process for District of Columbia parolees and supervised releasees who are arrested on warrants charging them with violations which may result in revocation and return to prison. The amended rules implement a consent decree issued by the U.S. District Court for the District of Columbia, in Long v. Gaines, Civil Action No. 01–0010 (EGS), dated December 17, 2002. This consent decree obliges the Commission to adopt as final rules the interim rules which the Commission published on January 18, 2002, and requires certain additional provisions relating to District of Columbia parolees who are arrested in jurisdictions outside the District of Columbia. The Commission has decided, in addition, to adopt the same procedures for District of Columbia supervised releasees. These procedures are intended to give the Commission a swift and efficient revocation hearing process which will minimize the Commission's use of the jail housing resources of the District of Columbia Department of Corrections, without impeding the Commission's ability to make a thorough assessment of the charges in each case.

DATES: This final rule will take effect February 24, 2003.

FOR FURTHER INFORMATION CONTACT: Michael A. Stover, Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959. Please note that questions about this **Federal Register** publication are welcome, but inquiries concerning individual cases cannot be answered.

SUPPLEMENTARY INFORMATION: In Long v. Gaines, 167 F. Supp. 2d 75 (D.D.C. 2001), the U.S. District Court for the District of Columbia held that the Parole Commission's rules governing the revocation process for District of Columbia parolees were unconstitutional with respect to the time deadlines for making determinations of probable cause and completing the revocation process. On December 17, 2002, the Court vacated its orders and judgment in Long v. Gaines, and entered a consent decree by which the Commission has agreed to withdraw its appeal to the U.S. Court of Appeals for the District of Columbia Circuit, and to adopt as final rules the rules which it adopted to carry out the compliance plan which the district court approved on November 21, 2001. The consent decree also includes certain additional provisions regarding DC Code parolees who are arrested in jurisdictions outside the District of Columbia.

Although the revocation hearing process adopted by these amended rules imposes deadlines for making probable cause and final revocation decisions which are shorter than the Commission believes to be required by the Constitution, the Commission believes that this approach makes sense in the context of a municipal correctional system with seriously strained jail housing resources. The shorter the average stay of each arrested parolee prior to a final disposition of the revocation charges, the faster the parolee can either be released or transferred to a Bureau of Prisons facility, thus limiting the total parolee population in the custody of the DC Department of Corrections at any given time. The most important feature of the revocation system which the Commission has developed as a result of Long v. Gaines is the rule which requires the scheduling of a fixed date for the revocation hearing as soon as probable cause is found, and which prohibits postponement requests submitted to the Commission less than fifteen days before a scheduled hearing except for compelling reasons. By reducing the possibilities for tactical delays which in the past made the Commission's revocation caseload in the District of Columbia nearly unmanageable, this rule permits the Commission to process a very substantial caseload in an orderly manner. An efficient revocation process also maximizes the Commission's ability to revoke the paroles of high-risk parole violators and expeditiously remove them from the community.

Under these amended rules, an examiner of the Commission will make a determination of probable cause no later than five days from arrest, and will hold a revocation hearing not later than 65 days from arrest. The examiner will also have the authority to order the release of the parolee if no probable cause is found, and to set a date for the revocation hearing if probable cause is found. The Commission will issue a final decision no later than 21 days from the revocation hearing (*i.e.*, 86 days from arrest). However, in the case of a parolee who admits all charges, waives the right to a local revocation hearing, or is convicted of a new crime, the Commission will conduct an ''institutional revocation hearing'' as provided in its original rules. The amended rules also require the Commission to ensure that: (1) Each parolee is given notice of the time and purpose of the probable cause hearing and the charged violations; (2) each parolee is provided, prior to the revocation hearing, with disclosure of the evidence to be relied upon by the Commission in determining whether parole was violated and, if so, whether to revoke parole; and (3) each parolee's arguments and evidence are given to the Commission before it renders a final decision.

With respect to parolees arrested outside the District of Columbia, but within the Washington DC Metropolitan Area, and who have not sustained new criminal convictions, the rules provide that an examiner of the Commission will conduct a probable cause hearing within five days of the parolee's arrival at a facility where probable cause hearings are conducted. Normally, the probable cause hearing will be conducted at the DC Jail following the transfer of the parolee from the local jail facility (in Maryland or Virginia) to which the parolee was taken immediately following arrest. The U.S. Marshals Service has issued instructions to all of its U.S. Marshals regarding timely notifications and transfers of parolees for probable cause hearings, which should make it possible for this new procedure to be successful.

Finally, the Commission has decided to extend the revocation procedures set forth in these rules to District of Columbia supervised release cases, even though District of Columbia supervised releasees are not members of the Long v. Gaines class and are not covered by the consent decree of December 17, 2002. (Sentences imposed for D.C. Code crimes committed within the District of Columbia since August 5, 2000, no longer include parole, but instead carry terms of supervised release which come under the Commission's jurisdiction.) In the Commission's judgment, these rules provide the most efficient revocation system for both parolees and supervised releasees in the District of Columbia, and correspondingly the best means of protecting the public safety.

Implementation

The Commission's regulations at 28 CFR 2.98 through 2.105, and 28 CFR 2.211 through 2.218, as amended by this

publication, will be followed by the Commission in the case of all District of Columbia Code parolees and supervised releasees who are arrested and held in the Washington, DC metropolitan area on warrants charging a violation or violations of parole or supervised release. In the case of District of Columbia Code parolees and supervised releasees who are arrested and held outside the Washington, DC metropolitan area on warrants charging a violation or violations of parole or supervised release, the revocation rules applicable to U.S. Code parolees shall apply. Where preliminary interviews are required, the Commission will request the local U.S. Probation Office to conduct a preliminary interview as required by 28 CFR § 2.48 (a) within 3 to 5 days of the Commission being notified by the U.S. Marshals Service of the parolee's arrest, unless exceptional circumstances require additional time not to exceed 10 days.

Regulatory Assessment Requirements

The U.S. Parole Commission has determined that these final rule amendments do not constitute a significant rule within the meaning of Executive Order 12866. The amended rules will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b), and are deemed by the Commission to be rules of agency practice that do not substantially affect the rights or obligations of non-agency parties pursuant to Section 804(3)(C) of the Congressional Review Act.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Prisoners, Probation and parole.

Adoption of Amended Rules

Accordingly, the interim rule amendments to 28 CFR Part 2, Subchapter C, Sections 2.98 through 2.105, which were published at 67 FR 2569 on January 18, 2002, are adopted by the Commission as final rules with revisions to Section 2.101 as set forth below. In addition, the Commission adopts amendments to 28 CFR Part 2, Subchapter D, which are also set forth below.

PART 2—[AMENDED]

1. The authority citation for 28 CFR Part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

2. Revise §2.101 (a) and (b), to read as follows:

§ 2.101 Probable cause hearing and determination.

(a) *Hearing.* A parolee who is retaken and held in custody in the District of Columbia on a warrant issued by the Commission, and who has not been convicted of a new crime, shall be given a probable cause hearing by an examiner of the Commission no later than five days from the date of such retaking. A parolee who is retaken and held in custody outside the District of Columbia, but within the Washington DC metropolitan area, and who has not been convicted of a new crime, shall be given a probable cause hearing by an examiner of the Commission within five days of the parolee's arrival at a facility where probable cause hearings are conducted. The purpose of a probable cause hearing is to determine whether there is probable cause to believe that the parolee has violated parole as charged, and if so, whether a local or institutional revocation hearing should be conducted. If the examiner finds probable cause, the examiner shall schedule a final revocation hearing to be held within 65 days of such parolee's arrest.

(b) *Notice and opportunity to postpone hearing.* Prior to the commencement of each docket of probable cause hearings in the District of Columbia, a list of the parolees who are scheduled for probable cause hearings, together with a copy of the warrant application for each parolee, shall be sent to the D.C. Public Defender Service. At or before the probable cause hearing, the parolee (or the parolee's attorney) may submit a written request that the hearing be postponed for any period up to thirty days, and the Commission shall ordinarily grant such requests. Prior to the commencement of the probable cause hearing, the examiner shall advise the parolee that the parolee may accept representation by the attorney from the D.C. Public Defender Service who is assigned to that docket, waive the assistance of an attorney at the probable cause hearing, or have the probable cause hearing postponed in order to obtain another attorney and/or witnesses on his behalf. In addition, the parolee may request the Commission to require the attendance of adverse witnesses (*i.e.*, witnesses who have given information upon which revocation may be based) at a postponed probable cause hearing. Such adverse witnesses may be required to attend either a postponed probable cause hearing, or a combined postponed probable cause and local revocation hearing, provided the parolee meets the requirements of § 2.102(a) for a local revocation hearing. The parolee shall also be given notice of the time and place of any postponed probable cause hearing.

* * * * *

3. Section 2.211 is amended as follows:

a. Amend paragraph (a) (1) by removing ''preliminary interview'' and adding in its place ''probable cause hearing'.

b. Revise paragraph (f) to read as follows:

§ 2.211 Summons to appear or warrant for retaking releasee.

* * * * *

(f) A summons or warrant issued pursuant to this section shall be accompanied by a warrant application (or other notice) stating:

(1) The charges against the releasee;

(2) The specific reports and other documents upon which the Commission intends to rely in determining whether a violation of supervised release has occurred and whether to revoke supervised release;

(3) Notice of the Commission's intent, if the releasee is arrested within the District of Columbia, to hold a probable cause hearing within five days of the releasee's arrest;

(4) A statement of the purpose of the probable cause hearing;

(5) The days of the week on which the Commission regularly holds its dockets of probable cause hearings at the Central Detention Facility;

(6) The releasee's procedural rights in the revocation process; and

(7) The possible actions that the Commission may take.

4. Section 2.212 is amended to read as follows:

a. Revise paragraph (b) to read as set forth below.

b. Amend paragraph (e) by removing ''preliminary interview'' and adding in its place ''probable cause hearing'.

§ 2.212 Execution of warrant and service of summons.

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(b) Upon the arrest of the releasee, the officer executing the warrant shall deliver to the releasee a copy of the warrant application (or other notice provided by the Commission) containing the information described in § 2.211(f).

* * * * *

5. Section 2.214 is revised to read as follows:

§ 2.214 Probable cause hearing and determination.

(a) *Hearing.* A supervised releasee who is retaken and held in custody in the District of Columbia on a warrant

issued by the Commission, and who has not been convicted of a new crime, shall be given a probable cause hearing by an examiner of the Commission no later than five days from the date of such retaking. A releasee who is retaken and held in custody outside the District of Columbia, but within the Washington D.C. metropolitan area, and who has not been convicted of a new crime, shall be given a probable cause hearing by an examiner of the Commission within five days of the releasee's arrival at a facility where probable cause hearings are conducted. The purpose of a probable cause hearing is to determine whether there is probable cause to believe that the releasee has violated the conditions of supervised release as charged, and if so, whether a local or institutional revocation hearing should be conducted. If the examiner finds probable cause, the examiner shall schedule a final revocation hearing to be held within 65 days of the releasee's arrest.

(b) *Notice and opportunity to postpone hearing.* Prior to the commencement of each docket of probable cause hearings in the District of Columbia, a list of the releasees who are scheduled for probable cause hearings, together with a copy of the warrant application for each releasee, shall be sent to the D.C. Public Defender Service. At or before the probable cause hearing, the releasee (or the releasee's attorney) may submit a written request that the hearing be postponed for any period up to thirty days, and the Commission shall ordinarily grant such requests. Prior to the commencement of the probable cause hearing, the examiner shall advise the releasee that the releasee may accept representation by the attorney from the D.C. Public Defender Service who is assigned to that docket, waive the assistance of an attorney at the probable cause hearing, or have the probable cause hearing postponed in order to obtain another attorney and/or witnesses on his behalf. In addition, the releasee may request the Commission to require the attendance of adverse witnesses (*i.e.*, witnesses who have given information upon which revocation may be based) at a postponed probable cause hearing. Such adverse witnesses may be required to attend either a postponed probable cause hearing, or a combined postponed probable cause and local revocation hearing, provided the releasee meets the requirements of § 2.215(a) for a local revocation hearing. The releasee shall also be given notice of the time and place of any postponed probable cause hearing.

(c) *Review of the charges.* At the beginning of the probable cause hearing, the examiner shall ascertain that the notice required by § 2.212(b) has been given to the releasee. The examiner shall then review the violation charges with the releasee and shall apprise the releasee of the evidence that has been submitted in support of the charges. The examiner shall ascertain whether the releasee admits or denies each charge listed on the warrant application (or other notice of charges), and shall offer the releasee an opportunity to rebut or explain the allegations contained in the evidence giving rise to each charge. The examiner shall also receive the statements of any witnesses and documentary evidence that may be presented by the releasee. At a postponed probable cause hearing, the examiner shall also permit the releasee to confront and cross-examine any adverse witnesses in attendance, unless good cause is found for not allowing confrontation. Whenever a probable cause hearing is postponed to secure the appearance of adverse witnesses (or counsel in the case of a probable cause hearing conducted outside the District of Columbia), the Commission will ordinarily order a combined probable cause and local revocation hearing as provided in paragraph (i) of this section.

(d) *Probable cause determination.* At the conclusion of the probable cause hearing, the examiner shall determine whether probable cause exists to believe that the releasee has violated the conditions of release as charged, and shall so inform the releasee. The examiner shall then take either of the following actions:

(1) If the examiner determines that no probable cause exists for any violation charge, the examiner shall order that the releasee be released from the custody of the warrant and either reinstated to supervision, or discharged from supervision if the term of supervised release has expired.

(2) If the hearing examiner determines that probable cause exists on any violation charge, and the releasee has requested (and is eligible for) a local revocation hearing in the District of Columbia as provided by § 2.215 (a), the examiner shall schedule a local revocation hearing for a date that is within 65 days of the releasee's arrest. After the probable cause hearing, the releasee (or the releasee's attorney) may submit a written request for a postponement. Such postponements will normally be granted if the request is received no later than fifteen days before the date of the revocation hearing. A request for a postponement that is received by the Commission less than fifteen days before the scheduled date of the revocation hearing will be granted only for a compelling reason. The releasee (or the releasee's attorney) may also request, in writing, a hearing date that is earlier than the date scheduled by the examiner, and the Commission will accommodate such request if practicable.

(e) *Institutional revocation hearing.* If the releasee is not eligible for a local revocation hearing as provided by § 2.215 (a), or has requested to be transferred to an institution for his revocation hearing, the Commission will request the Bureau of Prisons to designate the releasee to an appropriate institution, and an institutional revocation hearing shall be scheduled for a date that is within ninety days of the releasee's retaking.

(f) *Digest of the probable cause hearing.* At the conclusion of the probable cause hearing, the examiner shall prepare a digest summarizing the evidence presented at the hearing, the responses of the releasee, and the examiner's findings as to probable cause.

(g) *Release notwithstanding probable cause.* Notwithstanding a finding of probable cause, the Commission may order the releasee's reinstatement to supervision or release pending further proceedings, if it determines that:

(1) Continuation of revocation proceedings is not warranted despite the finding of probable cause; or

(2) Incarceration pending further revocation proceedings is not warranted by the frequency or seriousness of the alleged violation(s), and the releasee is neither likely to fail to appear for further proceedings, nor is a danger to himself or others.

(h) *Conviction as probable cause.* Conviction of any crime committed subsequent to the commencement of a term of supervised release shall constitute probable cause for the purposes of this section, and no probable cause hearing shall be conducted unless a hearing is needed to consider additional violation charges that may be determinative of the Commission's decision whether to revoke supervised release.

(i) *Combined probable cause and local revocation hearing.* A postponed probable cause hearing may be conducted as a combined probable cause and local revocation hearing, provided such hearing is conducted within 65 days of the releasee's arrest and the releasee has been notified that the postponed probable cause hearing will constitute his final revocation hearing. The Commission's policy is to conduct a combined probable cause and

local revocation hearing whenever adverse witnesses are required to appear and give testimony with respect to contested charges.

(j) *Late received charges.* If the Commission is notified of an additional charge after probable cause has been found to proceed with a revocation hearing, the Commission may:

(1) Remand the case for a supplemental probable cause hearing if the new charge may be contested by the releasee and possibly result in the appearance of witness(es) at the revocation hearing;

(2) Notify the releasee that the additional charge will be considered at the revocation hearing without conducting a supplemental probable cause hearing; or

(3) Determine that the new charge shall not be considered at the revocation hearing.

6. Section 2.215 (f) is revised to read as follows:

§ 2.215 Place of revocation hearing.

* * * * *

(f) A local revocation hearing shall be held not later than sixty-five days from the retaking of the releasee on a supervised release violation warrant. An institutional revocation hearing shall be held within ninety days of the retaking of the releasee on a supervised release violation warrant. If the releasee requests and receives any postponement, or consents to any postponement, or by his actions otherwise precludes the prompt completion of revocation proceedings in his case, the above-stated time limits shall be correspondingly extended.

* * * * *

7. Section 2.216 is amended by revising paragraph (e) and adding paragraphs (g) and (h) to read as follows:

§ 2.216 Revocation hearing procedure.

* * * * *

(e) All evidence upon which a finding of violation may be based shall be disclosed to the alleged violator before the revocation hearing. Such evidence shall include the Community Supervision Officer's letter summarizing the releasee's adjustment to supervision and requesting the warrant, all other documents describing the charged violation or violations, and any additional evidence upon which the Commission intends to rely in determining whether the charged violation or violations, if sustained, would warrant revocation of supervised release. If the releasee is represented by an attorney, the attorney shall be provided, prior to the revocation hearing, with a copy of the releasee's presentence investigation report, if such report is available to the Commission. If disclosure of any information would reveal the identity of a confidential informant or result in harm to any person, that information may be withheld from disclosure, in which case a summary of the withheld information shall be disclosed to the releasee prior to the revocation hearing.

* * * * *

(g) At a local revocation hearing, the Commission shall secure the presence of the releasee's Community Supervision Officer, or a substitute Community Supervision Officer who shall bring the releasee's supervision file if the releasee's Community Supervision Officer is not available. At the request of the hearing examiner, such officer shall provide testimony at the hearing concerning the releasee's adjustment to supervision.

(h) After the revocation hearing, the hearing examiner shall prepare a summary of the hearing that includes a description of the evidence against the releasee and the evidence submitted by the releasee in defense or mitigation of the charges, a summary of the arguments against revocation presented by the releasee, and the examiner's recommended decision. The hearing examiner's summary, together with the releasee's file (including any documentary evidence and letters submitted on behalf of the releasee), shall be given to another examiner for review. When two hearing examiners concur in a recommended disposition, that recommendation, together with the releasee's file and the hearing examiner's summary of the hearing, shall be submitted to the Commission for decision.

8. Section 2.217 (a) (1) is amended by removing ''preliminary interview'' and adding in its place ''probable cause hearing''.

9. Section 2.218 (g) is revised to read as follows:

§ 2.218 Revocation decisions.

* * * * *

(g) Decisions under this section shall be made upon the concurrence of two Commissioner votes, except that a decision to override an examiner panel recommendation shall require the concurrence of three Commissioner votes. The final decision following a local revocation hearing shall be issued within 86 days of the retaking of the releasee on a supervised release violation warrant. The final decision following an institutional revocation hearing shall be issued within 21 days of the hearing, excluding weekends and holidays.

Dated: January 16, 2003.

Edward F. Reilly, Jr.

Chairman, U.S. Parole Commission.

[FR Doc. 03–1593 Filed 1–23–03; 8:45 am]

BILLING CODE 4410–31–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 002–2003]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Interim Rule with Request for Comments.

SUMMARY: This interim rule with request for comments implements the Privacy Act of 1974, as amended (5 U.S.C. 552a, Pub. L. 93–579). This regulation exempts five Privacy Act systems of records of the Department of Justice, Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), from the subsections of the Privacy Act listed below. The five systems of records listed below are described in today's notice section of the **Federal Register**. As described in the rule, the exemptions are necessary to protect law enforcement and investigatory information and functions of ATF, and will be applied only to the extent that information in a record is subject to exemption pursuant to 5 U.S.C. 552a(j) and (k).

DATES: This rule is effective on January 24, 2003. Written comments must be submitted on or before March 25, 2003.

ADDRESSES: All comments concerning this interim rule should be mailed to: Mary Cahill, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (1400 National Place Building).

FOR FURTHER INFORMATION CONTACT: Mary Cahill (202) 307–1823.

SUPPLEMENTARY INFORMATION: On November 25, 2002, the President signed into law the Homeland Security Act of 2002, Pub. L. 107–296, 116 Stat. 2135 (2002). Under Title XI, Subtitle B of the Act, the ''authorities, functions, personnel, and assets'' of the Bureau of Alcohol, Tobacco, and Firearms are transferred to the Department of Justice, with the exception of certain enumerated authorities that were retained by the Department of the Treasury. The functions retained by the Department of the Treasury are the responsibility of a new Alcohol and Tobacco Tax and Trade Bureau. Section 1111 of the Homeland Security Act

further provides that the Bureau will retain its identity as a separate entity within the Department of Justice known as the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF). The transfer takes effect January 24, 2003.

In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, ATF is publishing its Privacy Act systems of records and converting certain ATF systems of records from Department of the Treasury systems to Department of Justice systems pursuant to the reorganization and transfer of ATF to the Department of Justice. (The publication of these systems of records as Justice systems does not rescind the Treasury/ATF systems of records, as they govern the Alcohol and Tobacco Tax and Trade Bureau within the Department of the Treasury.) There has been no change in the maintenance or operations of the systems of records by ATF, nor has there been a change in the exemptions claimed. Rather, these systems notices are being published to reflect the transfer of ATF to the Department of Justice.

Because the transfer of ATF to the Department of Justice is effective on January 24, 2003, it is necessary to immediately establish all appropriate exemptions to the Privacy Act in order to protect law enforcement and investigatory information and functions of ATF. These exemptions must be effective on January 24, 2003, the date of the transfer. It would be contrary to the public interest to allow the disclosure of information that could compromise ongoing investigations and law enforcement activities of the ATF. Accordingly, pursuant to the good cause exceptions found at 5 U.S.C. 553(b)(3)(B) and (d)(3), the Department finds that notice and public procedure on this rule are impracticable and contrary to the public interest.

After considering the comments received, the Department will issue a final rule.

Regulatory Flexibility Act

This interim rule relates to individuals, as opposed to small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act 5 U.S.C. 601–612, the interim rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 28 CFR Part 16

Administrative practices and procedures, Courts, Freedom of Information, and Privacy.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 793–78, it is proposed to amend 28 CFR part 16 as follows:

PART 16—[AMENDED]

Subpart E—Exemption of Records Systems under the Privacy Act

1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717, 9701.

2. Section 16.106 is added to subpart E to read as follows:

Subpart E—Exemptions of Records Systems Under the Privacy Act

§ 16.106 Exemption of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF)—Limited Access.

(a) The following system of records is exempt from 5 U.S.C. 552a(c)(3) and (4), (d)(1), (2), (3) and (4), (e)(1), (2), and (3), (e)(4)(G), (H) and (I), (e)(5) and (8), (f) and (g).

(1) Criminal Investigation Report System (JUSTICE/ATF–003).

(2) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(j)(2). Where compliance would not appear to interfere with or adversely affect the overall law enforcement process, ATF may waive the applicable exemption.

(b) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest not only of ATF, but also of the recipient agency. This would permit the record subject to take measures to impede the investigation, e.g., destroy evidence, intimidate potential witnesses or flee the area to avoid the thrust of the investigation.

(2) From subsection (c)(4) because an exemption being claimed for subsection (d) makes this subsection inapplicable.

(3) From subsections (d)(1), (e)(4)(G) and (H), (f) and (g) because these provisions concern individual access to investigative records, compliance with which could compromise sensitive information, interfere with the overall law enforcement process by revealing a pending sensitive investigation, possibly identify a confidential source or disclose information, including actual or potential tax information, which would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel.

(4) From subsection (d)(2) because, due to the nature of the information collected and the essential length of time it is maintained, to require ATF to amend information thought to be incorrect, irrelevant or untimely, would create an impossible administrative and investigative burden by forcing the agency to continuously retrograde its investigations attempting to resolve questions of accuracy, etc.

(5) From subsections (d)(3) and (4) because these subsections are inapplicable to the extent exemption is claimed from (d)(1) and (2).

(6) From subsection (e)(1) because: (i) It is not possible in all instances to determine relevancy or necessity of specific information in the early stages of a criminal or other investigation.

(ii) Relevance and necessity are questions of judgment and timing; what appears relevant and necessary when collected ultimately may be deemed unnecessary. It is only after the information is assessed that its relevancy and necessity in a specific investigative activity can be established.

(iii) In any investigation, ATF might obtain information concerning violations of law not under its jurisdiction, but in the interest of effective law enforcement, dissemination will be made to the agency charged with enforcing such law.

(iv) In interviewing individuals or obtaining other forms of evidence during an investigation, information could be obtained, the nature of which would leave in doubt its relevancy and necessity. Such information, however, could be relevant to another investigation or to an investigative activity under the jurisdiction of another agency.

(7) From subsection (e)(2) because the nature of criminal and other investigative activities is such that vital information about an individual can only be obtained from other persons who are familiar with such individual and his/her activities. In such investigations it is not feasible to rely upon information furnished by the individual concerning his own activities.

(8) From subsection (e)(3) because disclosure would provide the subject with substantial information that could impede or compromise the investigation. The individual could seriously interfere with undercover investigative activities and could take steps to evade the investigation or flee a specific area.

(9) From subsection (e)(4)(I) because the categories of sources of the records in these systems have been published in the **Federal Register** in broad generic terms in the belief that this is all that subsection (e)(4)(I) of the Act requires. In the event, however, that this subsection should be interpreted to require more detail as to the identity of sources of the records in these systems, exemption from this provision is necessary in order to protect the confidentiality of the sources of criminal and other law enforcement information. Such exemption is further necessary to protect the privacy and physical safety of witnesses and informants.

(10) From subsection (e)(5) because in the collection of information for law enforcement purposes it is impossible to determine in advance what information is accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light. The restrictions imposed by subsection (e)(5) would restrict the ability of trained investigators and intelligence analysts to exercise their judgment in reporting on investigations and impede the development of criminal intelligence necessary for effective law enforcement.

(11) From subsection (e)(8) because the notice requirements of this provision could seriously interfere with a law enforcement activity by alerting the subject of a criminal or other investigation of existing investigative interest.

(c) The following system of records is exempt from 5 U.S.C. 552a(c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H) and (I), and (f).

(1) Internal Security Record System (JUSTICE/ATF–006).

(2) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(k)(2) and (k)(5). Where compliance would not appear to interfere with or adversely affect the overall law enforcement process, ATF may waive the applicable exemption.

(d) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because to provide the subject with an accounting of disclosures of records in this system could inform that individual of the existence, nature, or scope of an actual or potential law enforcement investigation, and thereby seriously impede law enforcement efforts by permitting the record subject and other persons to whom he might disclose the records to avoid criminal penalties, civil remedies, or other measures.

(2) From subsection (d)(1) because disclosure of records in the system could reveal the identity of confidential sources and result in an unwarranted invasion of the privacy of others. Disclosure may also reveal information relating to actual or potential criminal investigations. Such breaches would restrict the free flow of information which is vital to the law enforcement process and the determination of an applicant's qualifications.

(3) From subsection (d)(2) because, due to the nature of the information collected and the essential length of time it is maintained, to require ATF to amend information thought to be incorrect, irrelevant or untimely, would create an impossible administrative and investigative burden by forcing the agency to continuously retrograde its investigations attempting to resolve questions of accuracy, etc.

(4) From subsections (d)(3) and (4) because these subsections are inapplicable to the extent exemption is claimed from (d)(1) and (2).

(5) From subsection (e)(1) because it is often impossible to determine in advance if investigative records contained in this system are accurate, relevant, timely, complete, or of some assistance to either effective law enforcement investigations, or to the determination of the qualifications and suitability of an applicant. It also is necessary to retain this information to aid in establishing patterns of activity and provide investigative leads. Information that may appear irrelevant, when combined with other apparently irrelevant information, can on occasion provide a composite picture of a subject or an applicant which assists the law enforcement process and the determination of an applicant's suitability qualifications.

(6) From subsection (e)(4)(G) and (H), and (f) because these provisions concern individual access to investigative records, compliance with which could compromise sensitive information, interfere with the overall law enforcement or qualification process by revealing a pending sensitive investigation, possibly identify a confidential source or disclose information which would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel. In addition, disclosure of information collected pursuant to an employment suitability or similar inquiry could reveal the identity of a source who provided information under an express promise of confidentiality, or could compromise the objectivity or fairness of a testing or examination process.

(7) From subsection (e)(4)(I) because the categories of sources of the records in these systems have been published in the **Federal Register** in broad generic terms in the belief that this is all that subsection (e)(4)(I) of the Act requires. In the event, however, that this subsection should be interpreted to require more detail as to the identity of sources of the records in these systems, exemption from this provision is necessary in order to protect the confidentiality of the sources of criminal and other law enforcement information. Such exemption is further necessary to protect the privacy and physical safety of witnesses and informants.

(e) The following system of records is exempt from 5 U.S.C. 552a(c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H) and (I), and (f).

(1) Personnel Record System (JUSTICE/ATF–007).

(2) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(k)(5). Where compliance would not appear to interfere with or adversely affect the overall law enforcement process, ATF may waive the applicable exemption.

(f) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal the existence, nature, or scope of an actual or potential personnel action. This would permit the record subject to take measures to hamper or impede such actions.

(2) From subsections (d)(1), (e)(4)(G) and (H), and (f) because many persons are contacted who, without an assurance of anonymity, refuse to provide information concerning a candidate for a position with ATF. Access could reveal the identity of the source of the information and constitute a breach of the promise of confidentiality on the part of ATF. Such breaches ultimately would restrict the free flow of information vital to a determination of a candidate's qualifications and suitability.

(3) From subsection (d)(2) because, due to the nature of the information collected and the essential length of time it is maintained, to require ATF to amend information thought to be incorrect, irrelevant or untimely, would

create an impossible administrative and investigative burden by forcing the agency to continuously retrograde its investigations attempting to resolve questions of accuracy, etc.

(4) From subsections (d)(3) and (4) because these subsections are inapplicable to the extent exemption is claimed from (d)(1) and (2).

(5) From subsection (e)(1) because:

(i) It is not possible in all instances to determine relevancy or necessity of specific information in the early stages of a personnel-related action.

(ii) Relevance and necessity are questions of judgment and timing; what appears relevant and necessary when collected ultimately may be deemed unnecessary. It is only after the information is assessed that its relevancy and necessity in a specific investigative activity can be established.

(iii)ATF might obtain information concerning violations of law not under its jurisdiction, but in the interest of effective law enforcement, dissemination will be made to the agency charged with enforcing such law.

(iv) In interviewing individuals or obtaining other forms of evidence during an investigation, information could be obtained, the nature of which would leave in doubt its relevancy and necessity. Such information, however, could be relevant to another investigation or to an investigative activity under the jurisdiction of another agency.

(6) From subsection (e)(4)(I) because the categories of sources of the records in these systems have been published in the **Federal Register** in broad generic terms in the belief that this is all that subsection (e)(4)(I) of the Act requires. In the event, however, that this subsection should be interpreted to require more detail as to the identity of sources of the records in these systems, exemption from this provision is necessary in order to protect the confidentiality of the sources of criminal and other law enforcement information. Such exemption is further necessary to protect the privacy and physical safety of witnesses and informants.

(g) The following systems of records are exempt from 5 U.S.C. 552a(c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H) and (I), and (f).

(1) Regulatory Enforcement Record System (JUSTICE/ATF–008).

(2) Technical and Scientific Services Record System (JUSTICE/ATF–009).

(3) These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(k)(2). Where compliance would not appear to interfere with or adversely affect the overall law enforcement process, ATF may waive the applicable exemption.

(h) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest, whether civil, criminal or regulatory, not only of ATF, but also of the recipient agency. This would permit the record subject to take measures to impede the investigation, *e.g.*, destroy evidence, intimidate potential witnesses or flee the area to avoid the thrust of the investigation thus seriously hampering the regulatory and law enforcement functions of ATF.

(2) From subsections (d)(1), (e)(4)(G) and (H), and (f) because these provisions concern individual access to investigative and compliance records, disclosure of which could compromise sensitive information, interfere with the overall law enforcement and regulatory process by revealing a pending sensitive investigation, possibly identify a confidential source or disclose information, including actual or potential tax information, which would constitute an unwarranted invasion of another individual's personal privacy, reveal a sensitive investigative technique, or constitute a potential danger to the health or safety of law enforcement personnel.

(3) From subsection (d)(2) because, due to the nature of the information collected and the essential length of time it is maintained, to require ATF to amend information thought to be incorrect, irrelevant or untimely, would create an impossible administrative and investigative burden by forcing the agency to continuously retrograde its investigations and compliance actions attempting to resolve questions of accuracy, etc.

(4) From subsections (d)(3) and (4) because these subsections are inapplicable to the extent exemption is claimed from (d)(1) and (2).

(5) From subsection (e)(1) because:

(i) It is not possible in all instances to determine relevancy or necessity of specific information in the early stages of a criminal, civil, regulatory, or other investigation.

(ii) Relevance and necessity are questions of judgment and timing; what appears relevant and necessary when collected ultimately may be deemed unnecessary. It is only after the information is assessed that its relevancy and necessity in a specific investigative or regulatory activity can be established.

(iii) In any investigation or compliance action ATF might obtain information concerning violations of law not under its jurisdiction, but in the interest of effective law enforcement, dissemination will be made to the agency charged with enforcing such law.

(iv) In interviewing individuals or obtaining other forms of evidence during an investigation, information could be obtained, the nature of which would leave in doubt its relevancy and necessity. Such information, however, could be relevant to another investigation or compliance action or to an investigative activity under the jurisdiction of another agency.

(6) From subsection (e)(4)(I) because the categories of sources of the records in these systems have been published in the **Federal Register** in broad generic terms in the belief that this is all that subsection (e)(4)(I) of the Act requires. In the event, however, that this subsection should be interpreted to require more detail as to the identity of sources of the records in these systems, exemption from this provision is necessary in order to protect the confidentiality of the sources of criminal, regulatory, and other law enforcement information. Such exemption is further necessary to protect the privacy and physical safety of witnesses and informants.

Dated: January 17, 2003.

Paul R. Corts,

Assistant Attorney General for Administration.

[FR Doc. 03–1575 Filed 1–23–03; 8:45 am]

BILLING CODE 4410–FB–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego 03–005]

RIN 2115–AA97

Safety Zone: San Diego Bay, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of San Diego Bay in support of the Gatorade January 24th Fireworks Show. This temporary safety zone is necessary to provide for the safety of the crews, spectators, participants of the event, participating vessels, other vessels, and users of the

waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 8:45 p.m. to 9:45 p.m. (PST) on January 24, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [COTP San Diego 03–005] and are available for inspection or copying at Marine Safety Office San Diego, 2716 North Harbor Drive, San Diego, CA 92101–1064 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Austin Murai, USCG, c/o U.S. Coast Guard Captain of the Port, telephone (619) 683–6495.

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. Final approval and permitting of this event were not issued in time to engage in full notice and comment rulemaking. Publishing a NPRM and delaying the effective date would be contrary to the public interest since the event would occur before the rulemaking process was complete.

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**. In addition to the reasons stated above, it would be contrary to the public interest not to publish this rule because the event has been permitted and participants and the public require protection.

Background and Purpose

Gatorade is sponsoring a fireworks show in San Diego Bay, CA on January 24, 2003. The fireworks show will be part of the weeklong Super Bowl XXXVII event known locally as the NFL Experience. The fireworks event involves one (1) barge, to be used as a platform for the launching of fireworks. This barge will be loaded with fireworks and thus contain a large amount of explosives. In order to establish a buffer around this hazardous situation, this rule will establish a safety zone around the barge. This temporary safety zone is necessary to provide for the safety of the crews, spectators, and participants of the Gatorade January 24th Fireworks Show. The proposed temporary safety zones are also necessary to protect other vessels and users of the waterway.

Discussion of Rule

This safety zone is necessary for the Gatorade January 24th Fireworks Show, which will take place on January 24, 2003 starting at 8:45 p.m. (PST) and ending at 9:45 p.m. (PST). The event involves one (1) barge, to be used as a platform for the launching of fireworks.

The temporary safety zone includes the area 120 yards around the fireworks barge anchored off of Southwest Marine Shipyard. The exact coordinates can be found in the regulatory text. This temporary zone will establish a safety buffer around the fireworks barge, which is necessary to provide for the safety of all involved in the event and other users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within these safety zones unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed safety zone would not have a significant economic impact on a substantial number of small entities because this zone is limited in scope and duration (in effect for only one (1) hour on January 24, 2003). Vessel traffic will still be able to pass around the zone. The Coast Guard will also issue broadcast notice to mariner alerts via VHF–FM marine channel 16 before the safety zone is enforced.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Petty Officer Austin Murai, Marine Safety Office San Diego at (619) 683–6495.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

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 create an environmental risk to health or risk to safety that may disproportionately affect children.

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.

To help the Coast Guard establish regular and meaningful consultation and collaboration with Indian and Alaskan Native tribes, we published a notice in the **Federal Register** (66 FR 36361, July 11, 2001) requesting comments on how to best carry out the Order. We invite your comments on how this proposed rule might impact tribal governments, even if that impact may not constitute a ''tribal implication'' under the Order.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this proposed rule and concluded that, under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.lD, this rule is categorically excluded from further environmental documentation because we are establishing a safety zone. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard is amending 33 CFR part 165 as follows:

PART 165— REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Add new § 165.T11–043 to read as follows:

§ 165.T11–043 Safety Zone; San Diego Bay, CA.

(a) *Location.* The temporary safety zone includes the area extending 120 yards around a point at 32° 41′08″N, 117° 08′51″W. All coordinates are North American Datum 1983.

(b) *Effective period.* This section will be enforced from 8:45 p.m. (PST) to 9:45 p.m. (PST) on January 24, 2003. If the event concludes prior to the scheduled termination time, the Captain of the Port will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. Mariners requesting permission to transit through the safety zone may request authorization to do so from the Patrol Commander. The Patrol Commander may be contacted via VHF–FM Channel 16.

Dated: January 15, 2003.

S.P. Metruck,

Commander, U.S. Coast Guard, Captain of the Port, San Diego.

[FR Doc. 03–1597 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego 03–002]

RIN 2115–AA97

Security Zone; Waters Adjacent to Embarcadero Park and Campbell Shipyard, San Diego, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the waters adjacent to Embarcadero Park and Campbell Shipyard, San Diego Bay, San Diego, CA. This temporary security zone is necessary to ensure the safety of the participants, spectators and users of the waterway during the National Football League Super Bowl XXXVII NFL Experience event. Persons and vessels are prohibited from entering into, transiting through, or anchoring within the security zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 8 a.m. (PDT) on January 18, 2003 to 2 a.m. (PDT) January 27, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket COTP San Diego 03–002 and are available for inspection or copying at U.S. Coast Guard Marine Safety Office San Diego, CA, 2716 N. Harbor Drive, San Diego, CA 92101, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer First Class Jeff Brown, Marine Safety Office San Diego, at (619) 683–6495.

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. Due to the complex planning for this event many details were not finalized in time to publish a notice of proposed rulemaking. Publishing a NPRM and delaying the effective date would be contrary to the public interest since the event would occur before the rulemaking process was complete.

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**. In addition to the reasons

stated above, it would be contrary to the public interest since action is needed to ensure the protection of the public and commercial structures and individuals near or in this structure during the National Football League Super Bowl XXXVII NFL Experience event.

Background and Purpose

Due to the high profile of the Super Bowl, this action is necessary to ensure public safety and prevent sabotage or terrorist acts against the public and commercial structures and individuals near or in this structure during the NFL Experience event to be held at Embarcadero Park and Campbell Shipyard.

The security zone consists of the navigable waters surrounding Embarcadero Park and Campbell Shipyard. The security zone follows along the northern portion of the designated channel in this area as to not impact traffic in the channel. The exact coordinates can be found in the regulatory text.

The zone will be in effect from 8 a.m. (PDT) on January 18, 2003 to 2 a.m. (PDT) January 27, 2003.

Coast Guard and San Diego Harbor Police will patrol and enforce the security zone. See 33 CFR 6.04–11, Assistance of other agencies.

Persons and vessels wishing to enter into or transit through this security zone are required to receive authorization by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule 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).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

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.

The Super Bowl committee has leased out the entire area affected by this Security zone with the exception to the Marriott Marina. The owners and operators of this marina will not be prohibited from transiting in and out of the marina at their leisure. All vessels will be authorized to transit through the zone after receiving permission from the Captain of the Port or his designated representative. Any vessel transiting through this zone is required to transit at a speed of not greater than 5 knots, excluding Coast Guard and Harbor Police vessels patrolling the security zone. Before the effective period, Marine Safety Office San Diego will issue maritime advisories to users of San Diego Bay.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule or if you have questions concerning its provisions or options for compliance, please contact Petty Officer First Class Jeff Brown, U.S. Coast Guard Marine Safety Office San Diego at (619) 683–6495. 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–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

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 create an environmental risk to health or risk to safety that may disproportionately affect children.

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.

To help the Coast Guard establish regular and meaningful consultation and collaboration with Indian and Alaskan Native tribes, we published a notice in the **Federal Register** (66 FR 36361, July 11, 2001) requesting comments on how to best carry out the Order. We invite your comments on how this proposed rule might impact tribal governments, even if that impact may not constitute a ''tribal implication'' under the Order.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (34)(g)), of Commandant Instruction M16475.lD, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record-keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. Add new temporary § 165.T11–040 is added to read as follows:

§ 165.T11–040 Security Zone, Waters adjacent to Embarcadero Park and Campbell Shipyard, San Diego, CA.

(a) *Location.* The security zone consists of the navigable waters surrounding Embarcadero Park and Campbell Shipyard. The security zone follows along the northern portion of the designated channel in this area as to not impact traffic in the channel. The limits of the security zone are more specifically defined as the area enclosed by the following points: starting on shore at 32° 42′30″ N, 117° 10′12″ W; then extending southwesterly to 32° 42′34″ N, 117° 10′22″ W; thence southerly to 32° 42′04″ N, 117° 10′08″ W; then southeasterly to 32° 42′09″ N, 117° 09′52″ W; then south to 32° 42′04″ N, 117° 09′44″ W, then easterly to a point on shore at 32° 42′08″ N, 117° 09′31″ W. All coordinates are North American Datum 1983.

(b) *Effective period.* The zone will be in effect from 8 a.m. (PDT) on January 18, 2003 to 2 a.m. (PDT) January 27, 2003. If the need for the security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of this security zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.33 of this part, entry into, transit through, or anchoring within the security zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. The San Diego Harbor Police may assist the Coast Guard in the patrol and enforcement of this security zone. Vessels requesting transit through the security zone will need to contact the Coast Guard patrol boat in the area via VHF-FM channel 16 prior to entering the zone. Upon authorization to enter the security zone, any vessel transiting through this zone is required to transit at a speed of not greater than 5 knots. All Coast Guard and Harbor Police vessels patrolling and enforcing the security zone are exempt from the 5 knot speed limit. All other general regulations of § 165.33 of this part apply in the security zone established by this temporary regulation.

Dated: January 15, 2003.

S.P. Metruck,

Commander, U.S. Coast Guard, Captain of the Port, San Diego, California.

[FR Doc. 03–1598 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego 03–004]

RIN 2115–AA97

Security Zone: Waters Adjacent to National City Marine Terminal, San Diego, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the waters adjacent to the National City Marine Terminal, San Diego Bay, San Diego, CA. This action is needed to protect the U.S. Naval vessel(s) and their crew(s) during a military outload evolution at the National City Marine Terminal from sabotage, or other subversive acts, accidents, criminal actions or other causes of a similar nature. Entry, transit, or anchoring in this zone is prohibited unless authorized by the Captain of the Port (COTP) San Diego, or his designated representative.

DATES: This rule is effective from 12 p.m. (noon) (PDT) on January 17, 2003 to 12 p.m. (noon) (PDT) on March 17, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket [COTP San Diego 03–004], and are available for inspection or copying at U.S. Coast Guard Marine Safety Office San Diego, 2716 N. Harbor Dr. San Diego CA, 92101, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Rick Sorrell, Chief of Port Operations, U.S. Coast Guard Marine Safety Office San Diego, at (619) 683–6495.

SUPPLEMENTARY INFORMATION:

Regulatory Information

This action is needed to protect the U.S. Naval vessel(s) and their crew(s) during a military outload evolution at the National City Marine Terminal from sabotage, or other subversive acts, accidents, criminal actions or other causes of a similar nature. This temporary security zone is necessary for protection of operations during a military outload in support of Operation Enduring Freedom in the area and for the protection of the operations from compromise and interference.

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 because it is not required in this instance. Any delay in implementing this rule would be contrary to the public interest since immediate action is necessary to ensure the protection of the vessel and their crews during a military outload as well as for the public and national security.

In keeping with the requirements of 5 U.S.C. 553(d) (3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**.

Due to complex planning, national security reasons, and coordination with all military schedules, information regarding the precise location and date of the event necessitating promulgation of this security zone and other logistical details surrounding the event were not provided until a date fewer than 30 days prior to the event. Due to the sensitive nature of the operations involved, it was

necessary for this information to be finalized at a later date.

Furthermore, in order to protect the interests of national security, the Coast Guard is promulgating this temporary regulation to provide safety and security of the U.S. Naval vessel(s) in the navigable waters of the United States. As a result, the enforcement of this security zone is a function directly involved in, and necessary to military operations. Accordingly, based on the military function exception set forth in the Administrative Procedure Act, 5 U.S.C. 553(a) (1), notice and comment rule-making and advance publication, pursuant to 5 U.S.C. 553(b) and (d), are not required for this regulation.

Background and Purpose

This action is needed to protect the U.S. Naval vessel(s) and their crew(s) during a military outload evolution at the National City Marine Terminal from sabotage, or other subversive acts, accidents, criminal actions or other causes of a similar nature. This temporary security zone is necessary for protection of operations during a military outload in the area and for the protection of the operations from compromise and interference.

The security zone consists of the navigable waters surrounding the National City Marine Terminal and encompassing Sweetwater Channel. The limits of this security zone are more specifically defined as the area enclosed by the following points: starting on shore at 32° 39′25″ N 117° 07′15″ W, then extending northerly to 32° 39′32″ N 117° 07′16″ W, then extending westerly to 32° 39′29″ N 117° 07′36″ W, then southerly to 32° 39′05″ N 117° 07′34″ W, and then easterly to shore at 32° 39′06″ N 117° 07′14.5″ W. All coordinates are North American Datum 1983.

This zone will be in effect from 12 p.m. (noon) (PDT) on January 17, 2003 to 12 p.m. (noon) (PDT) on March 17, 2003.

The security zone will be enforced by Coast Guard patrol craft and San Diego Harbor Police as enlisted by the COTP. See 33 CFR 6.04–11, Assistance of other agencies.

Persons and vessels are prohibited from entering into or transiting through this security zone unless authorized by the Captain of the Port, or his designated representative.

This security zone is established pursuant to the authority of the Magnuson Act regulations promulgated by the President under 50 U.S.C. 191, including subparts 6.01 and 6.04 of Part 6 of Title 33 of the Code of Federal Regulations. Vessels or persons violating this section are subject to he penalties set forth in 50 U.S.C. 192 which include seizure and forfeiture of the vessel, a monetary penalty of not more than $12,500, and imprisonment for not more than 10 years.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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).

Due to National Security interests, the implementation of this security zone is necessary for the protection of the United States and its people. The size of the zone is the minimum necessary to provide adequate protection for the U.S. Naval vessel(s), their crew(s), adjoining areas, and the public. Most of the entities likely to be affected are pleasure craft engaged in recreational activities and sightseeing. Any hardships experienced by persons or vessels are considered minimal compared to the national interest in protecting U.S. Naval vessel(s), their crew(s), and the public. Accordingly, full regulatory evaluation under paragraph 10 (e) of the regulatory policies and procedures of the DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

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. The Coast Guard coordinated with known private business owners in an effort to reduce any substantial impact on business.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they may better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule or if you have questions concerning its provisions or options for compliance, please contact Lieutenant Commander Rick Sorrell, Chief of Port Operations, U.S. Coast Guard Marine Office San Diego at (619) 683–6495.

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–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

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 create an environmental risk to health or risk to safety that may disproportionately affect children.

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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.lD, this rule is categorically excluded from further environmental documentation because we are establishing a security zone. A ''Categorical Exclusion Determination'' and checklist are available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record-keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. Add new temporary § 165.T11–042 is added to read as follows:

§ 165.T11–042 Security Zone; National City Marine Terminal, San Diego, CA.

(a) *Location.* The security zone consists of the navigable waters surrounding the National City Marine Terminal and encompassing Sweetwater Channel. The limits of this security zone are more specifically defined as the area enclosed by the following points: starting on shore at 32°39′25″ N 117°07′15″ W, then extending northerly to 32°39′32″ N 117°07′16″ W, then extending westerly to 32°39′29″ N 117°07′36″ W, then southerly to 32°39′05″ N 117°07′34″ W, and then easterly to shore at 32°39′06″ N 117°07′14.5″ W. All coordinates are North American Datum 1983.

(b) *Effective dates.* This security zone will be in effect from 12 p.m. (noon) (PDT) on January 17, 2003 to 12 p.m. (noon) (PDT) on March 17, 2003.

(c) *Enforcement.* This security zone is necessary to protect a military outload evolution which directly impacts national security. If the need for the security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of this security zone and will announce that fact via Broadcast Notice to Mariners.

(d) *Regulations.* In accordance with the general regulations in § 165.33 of this part, entry into, transit through, or anchoring within the security zone by all vessels is prohibited, unless authorized by the Captain of the Port, or his designated representative. All other general regulations of § 165.33 of this part apply in the security zone established by this section.

(e) The U.S. Coast Guard may be assisted in the patrol and enforcement of this security zone by the San Diego Harbor Police.

Dated: January 15, 2003.

S.P. Metruck,

Commander, U.S. Coast Guard, Captain of the Port, San Diego, California.

[FR Doc. 03–1599 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AK08

Payment or Reimbursement for Emergency Treatment Furnished at Non-VA Facilities

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document affirms amendments to VA's medical regulations establishing provisions for payment or reimbursement for certain non-VA emergency services furnished to veterans for nonservice-connected conditions. Those amendments were made by an interim final rule and were necessary to implement provisions of ''The Veterans Millennium Health Care and Benefits Act.'' Based on comments received from the public in response to the interim final rule, some changes are added for purposes of clarity.

DATES: Effective Date: March 25, 2003.

FOR FURTHER INFORMATION CONTACT: Roscoe Butler, Chief, Policy & Operations, Health Administration Service (10C3), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8302. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: An interim final rule amending VA's medical regulations at 38 CFR 17.1000–1008 was published in the **Federal Register** on July 12, 2001. These amendments implemented the provisions of section 111 of Public Law 106–117, The Veterans Millennium Health Care and Benefits Act. These statutory provisions, which are set forth at 38 U.S.C. 1725, authorize VA to establish provisions regarding payment of or reimbursement for the reasonable value of non-VA emergency services provided for nonservice-connected conditions of certain veterans who have no medical insurance and no other recourse for payment.

We provided a 60-day comment period that ended September 10, 2001 for comments on the interim final rule, including comments on the information collection provisions (except for the emergency information collection approval provisions which had a deadline for comments of July 19, 2001). We received no comments as to the emergency approval. Nevertheless, we did receive comments on the interim final rule and on the information collection provisions.

Conditions for Reimbursement or Payment for Emergency Services

One commenter requested clarification regarding when a facility will be considered to have held itself out as providing emergency care pursuant to § 17.1002(a). They believe that this language is unclear as currently written. No changes are made based on this comment. We believe that the current language is sufficiently descriptive to identify appropriate facilities that provide emergency services to the public without being unduly restrictive, especially in regard to facilities located in rural areas.

This commenter further stated agreement that veterans should be encouraged to seek care at the closest emergency department, regardless of whether it is a VA or other Federal facility, when they believe this is necessary. The commenter further stated that VA should also be aware that state and local Emergency Medical Services (EMS) regulations or ordinances may require that a patient always be taken to the closest emergency department, regardless of his or her status as a veteran. In such cases, they indicated that § 17.1002 (c) should be met. We concur with the comment, but no changes are made since, in our opinion, § 17.1002 (c) states that proposition and reasonably permits that interpretation under those facts.

Another commenter suggested that the inclusion of the parenthetical information in § 17.1002(d) may be redundant and therefore unnecessary. No change is made based on this comment. In our opinion, § 17.1002(d) appropriately interprets the legislative authority.

Another commenter suggested that VA clarify in § 17.1002(d) that the determination of a safe transfer is to be made solely by the attending emergency care physician provider. No change to § 17.1002 is made based on this comment. Section 17.1002(d) is concerned with review of claims for payment, not with clinical determinations concerning transfer of patients. Moreover, § 17.1006 already identifies the appropriate VA clinical officials who are responsible for making all needed medical determinations in connection with VA's review of a claim for reimbursement or payment of the costs of non-VA emergency treatment rendered to a veteran.

This commenter also suggested that VA clarify that payment or reimbursement may be made in situations where the veteran is discharged (as opposed to transfer). The commenter is concerned that § 17.1002(d) could be interpreted to preclude payment or reimbursement where the veteran was discharged after receiving emergency treatment. We agree and have incorporated that term as appropriate.

One commenter suggested that VA remove the 24-month requirement in § 17.1002(e) because otherwise VA may process numerous claims which will have to be denied due to the providers' inability to determine whether the veterans had received care during that time-period. Based on the comment, we believe modifying the certification requirement in § 17.1004(b) to exclude confirmation of enrollment status and receipt of VA care within the previous 24 months preceding the furnishing of the emergency care will clarify that the onus is not on the provider but, rather, on VA to certify this information. We believe this satisfies the commenter's concern.

Delegations of Authority

One commenter agrees that VA's physicians must make all clinical determinations required for purposes of § 17.1002. However, the commenter advises VA to instruct its physicians to apply a prudent lay person standard, not the higher standard of a medical professional, when making determinations under § 17.1002(b) and (c). No changes are made based on this comment. We believe the existing regulation adequately provides that the prudent lay person standard applies to both the initial evaluation and treatment of the emergent medical condition.

48-Hour Notice

One commenter stated that the 48-hour notice provision was too broad and should be amended to apply only to patients who are admitted to a facility for inpatient care. We concur and have changed that provision accordingly.

Claims

One commenter believes that the false claims notice in § 17.1004(b) should be eliminated since the current HCFA 1500 form includes a similar false claims notice. While we agree that the additional certification would not be necessary when the HCFA 1500 form is submitted, the rule allows for claims to be submitted on other standard medical billing forms, such as the UB92 form. Consequently, we have amended the rule to require the additional certification only when the form used does not contain a similar false claims notice.

Another commenter stated that requiring a separate written certification would preclude filing claims electronically. This commenter suggests that provisions be made to accept claims centrally and electronically to limit claims filing and processing costs. No changes are made based on this comment. VA is currently exploring centralizing the payment process and utilizing industry standards, such as electronic claims processing, fraud detection, and claims scrubbing.

One commenter states that VA's regulations provide for detailed timeframes for filing claims, but that there are no corresponding provisions establishing prompt payment by VA to claimants. No changes are made based on this comment. VA is studying the feasibility of centralizing the payment process, which would take into account prompt payment requirements.

One commenter indicated that filing a claim within the time periods of § 17.1004(d) is unrealistic. In support of his position, the commenter explains that in many emergency conditions the patient is unable to communicate coverage information to the provider when presenting for emergency care services. The commenter therefore recommends adding a provision to § 17.1004(d) to allow for claims to be submitted within 90-days after the date the veteran provided evidence to the facility/provider of emergency treatment of the veteran's eligibility for coverage under this rule.

No changes are made based on this comment. Adding such a provision would be at cross-purposes with this rule, which was designed to help ensure that claims are decided in a reasonable period of time. We believe that the rule provides ample time for the veteran, the veteran's family, or the veteran's legal representative to provide the required information, as the 90-day periods do not generally begin until after seminal events, *e.g.*, the veteran's discharge or death, by which time the veteran, the veteran's family, or the veteran's legal representative has been made aware of the veteran's personal liability for the non-VA emergency medical treatment rendered and the need to gather the veteran's insurance and other payment information.

Payment Limitations

Several commenters stated that § 17.1005(b) provides that reimbursement for payment for emergency treatment may be made only for the period from the beginning of the treatment until such time as the veteran could be transferred safely to a VA facility or other federal facility. They asked that we modify this statement by adding ''initial evaluation and'' before ''treatment.'' We concur with these

comments and have changed that provision accordingly.

Another commenter suggested that VA provide payment for emergency treatment sought by veterans under the prudent layperson standard in § 17.1002(b) from the beginning of treatment (including the evaluation) until the attending emergency physician provider determines the veteran is stabilized and may be safely transferred to a VA facility, other Federal facility, or discharged. No change to § 17.1002 is made based on this comment. Section 17.1006 already identifies the appropriate VA clinical officials who are responsible for making all needed medical determinations in connection with VA's review of a claim for reimbursement or payment for the costs of non-VA emergency treatment rendered to a veteran.

Further, this commenter believes that ''emergency treatment'' should be clarified to include ''evaluation'' of the condition. No change is made based on this comment. This is covered by the prudent layperson standard.

Another commenter strongly believes that VA should periodically re-examine the reimbursement rate under § 17.1005(a). That provision currently provides that VA will pay the lesser of the amount for which the veteran is personally liable or 70% of the amount under the applicable Medicare fee schedule. No change is made based on this comment. Medicare rates are adjusted annually. Consequently, VA's 70% rule will effectively reflect annual adjustments made to applicable Medicare rates.

Emergency Transportation

One commenter recommended that VA pay for emergency transportation services in cases where a ''prudent lay person'' would reasonably expect that the absence of such transport would result in placing the health of such individual in serious jeopardy. In the commenter's view, it would be unjust to hold the veteran liable for the cost of emergency transportation if they erroneously but reasonably believed those services were needed. No change is made based on this comment, which we interpret as essentially seeking to delete the limitations in § 17.1003. A claim for reimbursement for payment of emergency transport services under this section must, similar to other emergency medical services which are the subject of a claim under this rule, meet all the conditions of 38 U.S.C. 1725 to be reimbursable or payable at VA expense. We therefore do not make the recommended changes as the rule is consistent with statutory authority. We also note that because emergency transportation is subject to the requirements of 38 U.S.C. 1725, this section already incorporates a prudent lay person standard.

Paperwork Reduction Act

OMB has approved the information collections in §§ 17.004, 17.1007, and 17.1008 under control number 2900–0620. VA is not authorized to impose a penalty on persons for failure to comply with information collection requirements which do not display a current OMB control number, if required.

Compliance With the Congressional Review Act and E.O. 12866—Cost-Benefit Analysis

This rule is necessary to implement the provisions of section 111 of Public Law 106–117, The Veterans Millennium Health Care and Benefits Act. These provisions, which are set forth at 38 U.S.C. 1725, authorize VA to establish a mechanism for payment of or reimbursement for the reasonable value of non-VA emergency services provided for nonservice-connected conditions of certain veterans who have no medical insurance and no other recourse for payment. This rule would directly impact these veterans positively by avoiding full recourse or payment responsibility for medical care and resulting potential debt collection repercussions. This rule implements a detailed statutory mandate, and we found no potentially effective and reasonably feasible alternatives.

We estimate that the five-year cost of this rule from appropriated funds would be $2.1 billion in benefits costs and $21 million in government operating expenses. Since it is likely that the adoption of the rule may have an annual effect on the economy of $100 million or more, the Office of Management and Budget has designated this rule as a major rule under the Congressional Review Act, 5 U.S.C. 802, and an economically significant regulatory action under Executive Order 12866, Regulatory Planning and Review. The following information is provided pursuant to the Congressional Review Act and Executive Order 12866.

I. Benefits Costs

The estimated cost for implementation of the emergency care provisions of the Millennium Act are based on enrollment projections developed by a private actuarial firm and contained in the FY 2001 Enrollment Level Decision Analysis. This baseline population was adjusted, using a survey of enrollees and existing enrollment databases, to calculate the projected number of veterans who had no private or public insurance and who had used VA care within the previous 24 months. These adjustments reflect the criteria contained in the Millennium Act.

Private sector ER-related health care utilization was adjusted to reflect veteran enrollee demographics and relative morbidity, as well as uninsured enrollee reliance on the VA health care system. These utilization estimates, along with Medicare allowable charge levels, were applied to the estimated 990,000 veteran enrollees affected by the emergency care provisions. This resulted in projected estimates for emergency room visits ($93,480,145), ambulance use ($34,108,803), and ER-related inpatient care ($468,221,072). The total of $595,810,019 was then multiplied by the 70 percent reimbursement rate VA will use to pay emergency care providers. This comes to $417,067,014.

This total, however, reflects full implementation of the emergency care provisions. VA believes that it will take time before both providers and eligible veterans are aware of these new benefits and begin to submit acceptable bills to VA for reimbursement. Current experience shows that without widespread dissemination of information, there is limited use of these benefits. VA believes that with the publication of final regulations the submission of claims will increase significantly and could reach 50 percent of the full implementation costs in the first full year after the rule is in effect. Only experience will demonstrate the real demand for this new benefit.

II. Administrative Costs

The administrative workload caused by this rule is expected to be 241,457 claims filed in 2001. Administrative workloads assume that not all claims would be granted; it is probable that non-VA related claims will be received from veterans who are not eligible. Medical Care costs are computed on the average cost of a GS4/5 @ $12/hour × 30 minutes × 241,457 claims/60 which equals $1,448,742.00. In addition, the clinical review costs are estimated at $46/hour × 15 minutes × 241,457 claims/60 which equals $2,776,755.00 for total Medical Care costs of $4,225,497.

OMB Review

This document has been reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule would apply only to an extremely small amount of the business of a hospital or health care provider. Otherwise, the rule would only apply to individuals. Accordingly, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers for the programs affected by this rule are 64.005, 64.007, 64.008, 64,009, 64.010, 64.011, 64.012, 64.013, 64.014, 64.015, 64.016, 64.018, 64.019, 64.022, and 64.025.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: October 11, 2002.

Anthony J. Principi,

Secretary of Veterans Affairs.

Accordingly, the interim final rule amending 38 CFR part 17 which was published at 66 FR 36467 on July 12, 2001 is adopted as a final rule with the following changes:

PART 17—MEDICAL

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

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

§ 17.1000 [Amended]

2. The Note following § 17.1000 is amended by removing ''Health'' and adding, in its place, ''In cases where a patient is admitted for inpatient care, health''; and removing ''the veteran begins receiving'' and adding, in its place, ''admission for''.

§ 17.1002 [Amended]

3. In § 17.1002, paragraph (d) is amended by removing ''safely'' and adding, in its place, ''safely discharged or''.

§ 17.1004 [Amended]

4. In § 17.1004, paragraph (b) is amended by removing ''1500). The'' and adding, in its place, ''1500). Where the form used does not contain a false claims notice, the''; and by removing ''and 17.1003.'' and adding, in its place, ''(except for paragraph (e)) and 17.1003.''

§ 17.1005 [Amended]

5. In § 17.1005, paragraph (b) is amended by removing ''beginning of the'' and adding, in its place, ''beginning of the initial evaluation''; and by removing, ''transferred safely'', and adding, in its place, ''safely discharged or transferred''.

[FR Doc. 03–1577 Filed 1–23–03; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI112–01–7342b, FRL–7411–5]

Approval and Promulgation of Air Quality Implementation Plans; Wisconsin; Northern Engraving Environmental Cooperative Agreement

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a June 12, 2002, request from Wisconsin to revise its State Implementation Plan (SIP) for a source specific revision for Northern Engraving Corporation (NEC). Section 110 of the Clean Air Act (Act), 42 U.S.C. 7410, provides the authority for a state to provide a plan for the implementation, maintenance, and enforcement of the national ambient air quality standards in each air quality control region. The Wisconsin Department of Natural Resources (WDNR) and EPA entered into a memorandum of agreement concerning implementation of a joint cooperative pilot program and agreed to pursue regulatory innovation at two NEC facilities in Holmen, Wisconsin and Sparta, Wisconsin. Because portions of the Environmental Cooperative Agreement with NEC supercedes portions of rules in the Wisconsin SIP, a source-specific SIP revision is required.

DATES: This rule is effective on March 25, 2003, unless EPA receives adverse written comments by February 24, 2003. If EPA receives adverse comments, 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: You may inspect copies of the documents relevant to this action during normal business hours at the following location: United States Environmental Protection Agency Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

Send written comments to: Robert Miller, Chief, Permits and Grants Section, United States Environmental Protection Agency (AR–18J), 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Constantine Blathras at (312) 886–0671.

SUPPLEMENTARY INFORMATION: On March 25, 1999, the WDNR and the EPA entered into a memorandum of agreement concerning implementation of the joint state/EPA agreement to pursue regulatory innovation and the Wisconsin Environmental Cooperation Pilot Program. On June 7, 2002, Thomas V. Skinner, Regional Administrator, EPA Region 5, sent a letter to Darrell Bazzell, Secretary, WDNR, containing EPA's final response to the WDNR's innovation proposal for alternative permit conditions at the NEC facilities. The NEC facilities affected by this agreement are the Holmen facility, located at 1023 Sand Lake Road, Holmen, La Crosse County, Wisconsin, and the Sparta facility, located at 803 South Black River Street, Sparta, Monroe County, Wisconsin. Both La Crosse and Monroe counties are classified as unclassifiable/attainment for ozone, as of November 15, 1990. Volatile organic compounds are a precursor to ozone. Each facility's permit includes facility-wide emission rates for volatile organic compounds and hazardous air pollutants.

The innovative components of the proposal for the NEC Sparta and Holmen facilities include: (1) Waiver from the requirements that facilities obtain a new permit prior to

construction; (2) waiver from the requirement that facilities receive an appropriate permit prior to operating new process equipment; (3) waiver in the facilities' minor source permits of individual process line latest available control technology requirements for controlling volatile organic compound emissions; and (4) record keeping and reporting flexibility.

The Environmental Cooperative Agreement, specifically section XII (Operational Flexibility and Variances), proposes to establish new requirements for the two NEC facilities. The proposed new requirements would replace or revise certain requirements that might otherwise apply to those sources. Some of the requirements to be replaced or revised are currently embodied in Wisconsin's SIP for meeting air quality objectives. In such cases, the proposed flexibility in the Environmental Cooperative Agreement cannot be granted by WDNR unless the new requirements are first approved by EPA as a source-specific revision to the SIP.

The WDNR submitted the following portions of Section XII of the Environmental Cooperative Agreement (Operational Flexibility and Variances) as a source-specific SIP revision:

1. *Item:* Waiver from the requirements to obtain a construction permit prior to commencing construction of new process equipment, commencing modification of existing equipment, or relocating existing process equipment of a minor stationary source between the facilities covered by this Agreement.

Previous Requirements Superseded by this Agreement: Requirement to obtain a construction permit prior to construction, reconstruction, replacement, relocation of modification of a minor stationary source that is not otherwise exempt under section Natural Resources (NR) 406.04, Wisconsin Administrative (Wis. Adm.) Code. (NR 406.03, Wis. Adm. Code)

New Requirement

a. New Equipment Construction and Modification: The permittee may commence construction or modification (but not operation) of new process equipment prior to obtaining a construction permit, provided the following conditions are met. These conditions do not apply if a proposed project is exempt from the requirement to obtain a construction permit, pursuant to section NR 406.04, Wis. Adm. Code. (section 299.80(2)(h) and (4)(b), Wisconsin Statutes (Wis.Stats.))

(1) The permittee shall submit the following information to the Department of Natural Resources, La Crosse Area Office, 3550 Mormon Coulee Road, Room 104, La Crosse, WI 54601 or other location specified by the Department:

(a) Two copies of a complete construction and operating permit application describing the proposed equipment;

(b) An application fee of $1,350 or other amount as required by section NR 410.03(1)(d), Wis. Adm. Code; and

(c) Information describing how the interested persons group was notified of the proposed project. (sections 299.80(10) and (11)(b), Wis. Stats.)

(2) The Department shall process the permit application in accordance with sections 285.60 through 285.69, Wisconsin Statutes and sections NR 406 and NR 407, Wis. Adm. Code, however, the permittee need not wait for permit issuance to commence construction. The Department shall process the permit application as both a construction permit and a significant revision to the operation permit, and issue both permits simultaneously to reduce the administrative burden of issuing a construction permit that expires 18 months after issuance followed by an operation permit. The Department shall send an invoice outlining the fees required for processing the construction permit for the proposed project, including the fees for an expedited permit review authorized under section NR 410.03(o), Wis. Adm. Code, less the $1,350 permit application fee. (sections 299.80(2)(h), (4)(b), (10) and (11)(b), Wis. Stats.)

(3) The permittee shall pay the total amount of the fee invoice within 30 days of receipt.[1] (s. 299.80(10), Wis. Stats.)

(4) The permittee shall continue to comply with all the requirements of Part I.A. of the permit so long as the cooperative agreement is in affect.[2] (s. 299.80(2)(h) and (4)(b), Wis. Stats.)

(5) Nothing in this section or in any Cooperative Agreement between the Department and the permittee shall be construed as a guarantee that the Department will issue an air pollution control construction and operation permit for a proposed project. The decision on whether to approve a permit application will be made according to the requirements of chapters NR 400 through NR 499, Wis. Adm. Code and s. 285.60 through 285.69, Wis. Stats. If the Department denies a permit application pursuant to ss 285.61 through 285.64, Wis. Stats. all costs and risks associated with installing and operating the proposed equipment shall be incurred solely by the permittee. In the event that the construction and operation permit application for the proposed project is denied, the permittee shall cease construction of the equipment in question immediately.

b. New Equipment Operation: The permittee may operate new process equipment, provided one of the following alternate scenarios are met. The conditions do not apply if a proposed project is exempt from the requirement to obtain a construction permit, pursuant to s. NR 406.04, Wis. Adm. Code. (s. 299.80(2)(h) and (4)(b), Wis. Stats.)

(1) Alternate Scenario #1: The permittee may operate new process equipment provided the permittee submits a complete construction and operation permit application as required by the conditions of I.A.5.a. *and* the Department issues a construction permit pursuant to ss. 285.60 through 285.69, Wis. Stats and ss. NR 406 and NR 407, Wis. Adm. Code. The permittee shall operate the new process equipment in compliance with the conditions contained in any construction permit issued by the Department. (s. NR 406.03, Wis. Adm. Code)

(2) Alternate Scenario #2: The permittee may initially operate new process equipment prior to obtaining a construction permit provided the permittee submits a complete

[1] Pursuant to s. 299.80(10), Wis. Stats., a participant in a cooperative agreement shall pay the same fees required under chs. 280 to 295, Wis. Stats. that it would be required to pay if it had not entered into a cooperative agreement. Therefore, while the requirement to obtain a construction permit prior to installation is waived, the permittee is still required to pay the fees that would have been assessed had a construction permit been issued under ch. NR 406, wis. Adm. Code.

[2] By continuing to comply with the facility wide emission limitations outlined in Part I.A., the net emissions increase from any new sources or relocation of any existing sources from other facilities will not exceed the major stationary source levels of s. NR 405.02(22)(a), Wis. Adm. Code triggering Prevention of Significant Deterioration (PSD) Requirements. The existing facility potential emissions of all criteria pollutants are less than 250 tons per year and the facility is not included in the source categories listed in s. NR 405.07(4), Wis. Adm. Code. Therefore, the existing facility is a synthetic minor source for PSD purposes. Note: This facility is not located in an area designated nonattainment. Also, by continuing to comply with the facility wide emissions limitations, the potential emissions increase from any new sources or relocated existing sources will not exceed 100 tons per year after controls for any criteria pollutant. Therefore none of the changes will be considered a Type II action requiring an environmental assessment. Finally, by continuing to comply with the facility wide emission limitations, the facility will not become a major source for the Operating Permits Program under 40 CFR Part 70 (Part 70) purposes for either volatile organic compound or hazardous air pollutant emissions. Requirement I.A.5.a.(1)(g) of the permit requires that any changes that result in potential facility wide emissions of particulate matter, sulfur dioxide, nitrogen oxide or carbon monoxide emissions exceeding 100 tons per year, must follow permit issuance requirements of chs. NR 406 and NR 407, Wis. Adm. Code.

construction and operation permit application as required by the conditions of I.A.5.a. *and* the following conditions are met: (s. 299.80(2)(h) and (4)(b), Wis. Stats.)

(a) The permittee shall submit two copies of the following information to the Department of Natural Resources, La Crosse Area Office, 3550 Mormon Coulee Road, Room 104, La Crosse, WI, 54601 *or* other location specified by the Department, 14 calendar days prior to the date of initial operation:

(i) Information identifying all applicable requirements from the Wisconsin Statutes, Wisconsin Administrative Code, and the Act for the proposed equipment;

(ii) A quantification of the air pollution emissions that would result from the proposed project;

(iii) A computer dispersion modeling analysis showing the National Ambient Air Quality Standards will be protected if the proposed project results in an increase in potential particulate matter, sulfur dioxide, nitrogen oxide, and/or carbon monoxide emissions.

(iv) A computer dispersion modeling analysis showing the Acceptable Ambient Concentrations will be protected if the proposed project results in an increase in emissions of any hazardous air pollutant listed in ch. NR 445, Wis. Adm. Code so that the resulting facility total emissions of the hazardous air pollutant are above the corresponding Table Value(s) OR results in the emission of any hazardous air pollutant listed in ch. NR 445, Wis. Adm. Code that was not previously emitted, at a rate greater than its corresponding Table Value(s); and

(v) An analysis showing the proposed project will not cause the total facility wide potential emissions of particulate matter, sulfur dioxide, nitrogen oxides or carbon monoxide to exceed 100 tons per year. Any proposed new or relocated source that will result in the facility wide potential emissions of any one of these pollutants exceeding 100 tons per year is not eligible for this waiver. If the facility wide potential emissions of any one of the pollutants would be greater than 100 tons per year as the result of a proposed project, the permittee shall comply with the construction permit requirements outlined in ch. NR 406, Wis. Adm. Code and the significant operation permit revision requirements of s. NR 407.13, Wis. Adm. Code.[3] (ss. 299.80(10) and (11)(b), Wis. Stats.)

(b) The Department has 14 calendar days from the date that all the information outlined in (a) is received to request additional information or object to the proposed project. If the Department requests additional information during the original 14 calendar day period the Department shall have an additional 7 calendar days from the date of receipt of the information to request additional information or object to the proposed project. Under no scenario shall the Department have less than 14 days to review original submittal. If the Department does not respond within 14 calendar days from the date that all the information outlined in (a) is submitted, or within 7 days from the date that any additional information requested by the Department is submitted, whichever is later, the permittee may commence initial operation of the proposed equipment. The Department may provide written approval to commence initial operation of the proposed equipment prior to the end of the 14 calendar day period. If this is the case the permittee may commence initial operation upon receipt of this written approval. (ss. 299.80(2)(h) and (11)(b), Wis. Stats.)

(3) *Alternate Scenario #3:* The permittee may initially operate new process equipment prior to obtaining a construction permit provided the permittee submits a complete construction and operation permit application as required by the conditions of I.A.5.a. *and* the following conditions are met: (s. 299.80(2)(h) and (4)(b), Wis. Stats.)

(a) The Department provides written approval to commence initial operation of the proposed equipment. This written approval shall only be provided after the Department completes an air quality dispersion modeling analysis to ensure that the national ambient air quality standards and acceptable ambient concentrations will be protected while the proposed equipment is operating; (s. NR 406.09, Wis. Adm. Code)

(b) The permittee shall comply with any specific conditions included in the Department's written approval to commence initial operation;

(4) The permittee shall continue to comply with all the requirements of Part I.A. of this permit so long as the cooperative agreement is in affect.[4] (s. 299.80(2)(h) and (4)(b), Wis. Stats.)

(5) Nothing in this section or in any Cooperative Agreement between the Department and the permittee shall be construed as a guarantee that the Department will issue an air pollution control construction and operation permit for a proposed project. The decision on whether to approve a permit application will be made according to the requirements of chapters NR 400 through NR 499, Wis. Adm. Code and s. 285.60 through 285.69, Wis. Stats. If the Department denies a permit application pursuant to ss 285.61 through 285.64, Wis. Stats. all costs and risks associated with installing and operating the proposed equipment shall be incurred solely by the permittee. In the event that the construction and operation permit application for the proposed project is denied, the permittee shall cease construction and/or operation of the equipment in question immediately.

2. Item: *(Sparta Only—Processes P32, P33, P56, P42, and P44)* Waiver from the requirements for Processes P32, P33, P56, P42 and P44 at the Sparta facility to comply with the reasonable available control technology (RACT) requirements for controlling volatile organic compound emissions. *Previous Requirements Superseded by this Agreement (source of the requirement):*

(1) *3 Roll Coating Machines P32:* Requirement to limit volatile organic compound emissions from a miscellaneous metal parts or products coating line using baked or specially cured coating technology to not more

[3] This requirement is necessary because if the potential emissions of particulate matter, sulfur dioxide, nitrogen oxide or carbon monoxide emissions exceed 100 tons, the facility would be considered a major source for Part 70 purposes and would be required to obtain either a Part 70 source permit or a synthetic minor, non-Part 70 source permit containing conditions that limit the potential emissions of all criteria pollutants to less than 100 tons per year.

[4] By continuing to comply with the facility-wide emission limitations outlined in Part I.A., the net emissions increase from any new sources or relocation of any existing sources from other facilities will not exceed the major stationary source levels of s. NR 405.02(22)(a), Wis. Adm. Code triggering Prevention of Significant Deterioration (PSD) Requirements. The existing facility potential emissions of all criteria pollutants are less than 250 tons per year and the facility is not included in the source categories listed in s. NR 405.07(4), Wis. Adm. Code, therefore the existing facility is a synthetic minor source for PSD purposes. Note: This facility is not located in an area designated nonattainment. Also, by continuing to comply with the facility wide emissions limitations, the potential emissions increase from any new sources or relocated existing sources will not exceed 100 tons per year after controls for any criteria pollutant. Therefore none of the changes will be considered a Type II action requiring an environmental assessment. Finally, by continuing to comply with the facility wide emission limitations, the facility would not become a major source for Part 70 purposes for either volatile organic compound or hazardous air pollutant emissions. Requirement I.A.5.a.(1)(g) of this permit requires that any changes that result in potential facility wide emissions of particulate matter, sulfur dioxide, nitrogen oxide or carbon monoxide emissions exceeding 100 tons per year follow permit issuance requirements of chapters NR 406 and NR 407, Wis. Adm. Code.

than: (a) 4.3 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies clear coatings; (b) 3.5 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies extreme performance coatings; (c) 3.0 pounds per gallon of coating, excluding water, delivered to a coating applicator for all other coatings. (s. *NR 422.15(2), Wis. Adm. Code, the Specific Emission Limitation for volatile organic compounds in condition I.C.1. and conditions I.C.2.c., I.C.2.d., and I.C.2.e of Air Pollution Control Permit 92–POY–157 and the Specific Emission Limitation for volatile organic compounds in condition I.A.1. and conditions I.A.2.c., I.A.2.d., and I.A.2.e. of Air Pollution Control Permit 91–POY–088)*

(2) *2 Metal Spray Booths P33:* Requirement to limit volatile organic compound emissions from a miscellaneous metal parts or products coating line using baked or specially cured coating technology to not more than: (a) 4.3 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies clear coatings; (b) 3.5 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies extreme performance coatings; (c) 3.0 pounds per gallon of coating, excluding water, delivered to a coating applicator for all other coatings. (*s. NR 422.15(2), Wis. Adm. Code, the Specific Emission Limitation for volatile organic compounds in condition I.A.1. and conditions I.A.2.c., I.A.2.d., and I.A.2.e. of Air Pollution Control Permit 91–POY–157, and the Specific Emission Limitation for volatile organic compounds in condition I.D.1. of Air Pollution Control Permit 91–POY–088.*)

(3) *Roll Coating Line with Electric Oven P56:* Requirement to limit volatile organic compound emissions from a miscellaneous metal parts or products coating line using baked or specially cured coating technology to not more than: (a) 4.3 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies clear coatings; (b) 3.5 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies extreme performance coatings; (c) 3.0 pounds per gallon of coating, excluding water, delivered to a coating applicator for all other coatings. (*s. NR 422.15(2), Wis. Adm. Code, the Specific Emission Limitation for volatile organic compounds in condition I.F.1. and conditions I.F.2.c. of Air Pollution Control Permit 93–IRS–040.*)

(4) *Two Roll Coaters with Two Electric Drying Ovens P42:* Requirement to limit volatile organic compound emissions from a miscellaneous metal parts or products coating line using baked or specially cured coating technology to not more than: (a) 4.3 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies clear coatings; (b) 3.5 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies extreme performance coatings; (c) 3.0 pounds per gallon of coating, excluding water, delivered to a coating applicator for all other coatings. (*s. NR 422.15(2), Wis. Adm. Code.*)

(5) *Spray Booth P44:* Requirement to limit volatile organic compound emissions from a miscellaneous metal parts or products coating line using baked or specially cured coating technology to not more than: (a) 4.3 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies clear coatings; (b) 3.5 pounds per gallon of coating, excluding water, delivered to a coating applicator that applies extreme performance coatings; (c) 3.0 pounds per gallon of coating, excluding water, delivered to a coating applicator for all other coatings. (*s. NR 422.15(2), Wis. Adm. Code.*)

New Requirement: Volatile organic compound emissions from the entire Northern Engraving Corporation, Sparta facility may not exceed 85 tons per year averaged over each 12 consecutive month period.

3. *Item:* Waiver from individual process line latest available control technique (LACT) requirements for controlling volatile organic compound emissions.

Previous Requirements Superseded by this Agreement (source of the requirement): Requirement to control volatile organic compound emissions from process lines on which construction or modification commenced on or after August 1, 1979, and which are not subject to emission limitations listed elsewhere in chs. NR 419 to 423, by at least 85 percent or where 85 percent control had been demonstrated to be technologically infeasible, to control volatile organic compounds using the latest available control techniques and operating practices demonstrating best current technology, as approved by the Department. (*s. NR 424.03(2)(b) and (c), Wis. Adm. Code*)

Holmen—LACT Permit Requirements

Process P03: Permit 91–POY–126—Condition: I.D.1.

Specific Emission limitation for VOCs Process P08: Permit 91–POY–126—Condition: I.E.1.

Specific Emission Limitation for VOCs Process P09: Permit: 91–POY–126—Condition: I.A.1.

Specific Emission Limitation for VOCs Alteration EOP–10–KJC–83–32–081 dated May 27, 1987 for PSMG–04, PSO–21H, PSO–11–H, PSO–12–H, PSO–18–H and PSO–19–H

Alteration of EOP–10–JKC–83–32–081 dated February 12, 1985 Condition: I.A.44.Emission Limitation for Organic Compounds and I.A.50. Emission Limitation for Organic Compounds EOP–10–JKC–83–32–081—Condition: I.A.38. Emission Limitation of Organic Compounds, I.A.39. Emission Limitation of Organic Compounds, I.A.42. Emission Limitation for Organic Compounds Process P50: s. NR 424.03(2)(b) and (c), Wis. Adm. Code

Sparta—LACT Permit Requirements

Process P30: Permit 642025010–N01—Condition: I.A.2.

Specific Emission Limitation for VOCs EOP–10–KJC–83–42–077—Condition:I.A.5.

Specific Emission Limitation for VOCs Process P37: Permit 92–POY–068—Condition: I.B.

Specific Emission Limitation for VOCs EOP–10–KJC–83–32–077A—Condition I.A.4.

Specific Emission limitation for VOCs EOP–10—KJC–83–32–077—Condition I.A.8.

Specific Emission Limitation for VOCs Process P57: Permit 64025010–N01—Condtion I.A.1.

Specific Emission Limitation for VOCs Process P91: Permit 93–IRS–040—Condition I.D.1.

Specific Emission Limitation for VOCs
Process P41: s. NR 424.03(2)(b) and (c), Wis. Adm. Code
Process P42: s. NR 424.03(2)(b) and (c), Wis. Adm. Code
Process P43: s. NR 424.03(2)(b) and (c), Wis. Adm. Code
Process P44: s. NR 424.03(2)(b) and (c), Wis. Adm. Code

New Requirement: Volatile organic compound emissions from each of the Sparta and Holmen NEC facilities may not exceed 85 tons per year averaged over each 12 consecutive month period.

4. *Item:* Monthly rather than daily record keeping requirements and six month emission reporting.

Previous Requirements Superseded by this Agreement (source of the requirement): The following permit conditions require Northern Engraving to keep daily records:

Holmen—Daily Recordkeeping Requirements

Section NR 439.04(3), Wis. Adm.

Code

Permit 91–POY–126—Condition I.II.5. Alteration of permit EOP–10–KJC–83–32–081 dated 2/20/90 Condition I.B.13.

Sparta—Daily Recordkeeping Requirements

Sections NR 439.04(5)(e) and (g) and NR 439.04(3), Wis. Adm. Code

Permit 92–POY–157—Conditions I.I.A.2.b., I.I.A.2.f., I.I.A.2.g., I.I.C.2.b., I.I.C.2.f., and I.I.C.2.g.

Permit 91–POY–088—Conditions I.I.A.2.b., I.I.A.2.d., and I.I.A.2.e.

Permit 93–IRS–040—Condition I.I.F.2.b.

New Requirement: To demonstrate compliance status with the facility wide emission limitations for volatile organic compounds and hazardous air pollutants, NEC would be required to keep monthly records of emissions from each facility and report actual emission every 6 months as follows:

(1) Each month the permittee shall calculate the total volatile organic compound emissions from the facility as follows:

$$E = (1\ \text{ton}/2000\ \text{lbs}) \times \{[(U_1 \times W_1 \times C_1) + (U_2 \times W_2 \times C_2) + \ldots + (U_n \times W_n \times C_n)] - [(S_1 \times P_1) + (S_2 \times P_2) + \ldots + (S_m \times P_m)]\}$$

where:

E is the monthly VOC emissions (tons/month);

U is the monthly usage of each ink, coating, solvent, or other VOC containing material used during the month (gallons/month);

W is the density of each ink, coating, solvent, or other VOC containing material used during the month (pounds/gallon)

C is the VOC content of each ink, coating, solvent, or other VOC containing material used during the month expressed as a weight fraction (*i.e.* if a material is 25% VOC by weight C would be 0.25);

n identifies each ink, coating, solvent or other VOC containing material used during the month;

S is the amount of each spent ink, coating, solvent or other VOC containing material recovered and shipped off site each month (gallons/month);

P is the VOC content of each spent ink, coating, solvent or other VOC containing material recovered and shipped off site each month in pounds per gallon;

m identifies each spent ink, coating, solvent or other VOC containing material recovered and shipped off site during the month. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(2) To demonstrate compliance with condition I.A.1.a.(1), the permittee shall calculate the total volatile organic compound emissions from the facility over each 12 consecutive month period by summing the monthly volatile organic compound emissions as calculated in I.A.1.b.(1) for each consecutive 12-month period. This calculation shall be performed within 20 calendar days of the end of each month for the previous 12 consecutive month period. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(3) The permittee shall use U.S. EPA Method 24, or coating manufacturer's formulation data to determine the VOC content (Cn) and the density (Wn) of the inks, coatings, solvents or other VOC containing materials used. In case of an inconsistency between the Method 24 results and the formulation data, the Method 24 results will govern. (s. NR 439.04(1)(d), Wis. Adm. Code)

(4) The permittee shall analyze the spent ink, coating, solvent and other VOC containing material recovered and shipped off site to determine the VOC content (P) no less than: (a) each time there is a substantial change to materials or process operations that may affect the characteristics of the waste stream; or (b) quarterly, which ever is most frequent. (s. NR 439.04(1)(d), Wis. Adm. Code)

(5) The permittee shall keep records of the following for each ink, coating, solvent, or other VOC containing material used at the facility:

(a) A unique name or identification number; and

(b) The VOC content, expressed as a weight fraction (C_n). (s. NR 439.04(1)(d), Wis. Adm. Code)

(6) The permittee shall keep monthly records of:

(a) The amount of each ink, coating, solvent, or other VOC containing material used in gallons per month (U_n);

(b) The density of each ink, coating, solvent, or other VOC containing material used in pounds per gallon (W_n);

(c) The amount of spent ink, coating, solvent, or other VOC containing material recovered and shipped off site in gallons per month (S_m);

(d) The VOC content of each spent ink, coating, solvent or other VOC containing material recovered and shipped off site in pounds per gallon (P_m).

(e) The total monthly VOC emissions from the facility in tons per month (E), as calculated in I.A.1.b.(1); and

(f) The total VOC emissions from the facility in tons per year as calculated in I.A.1.b.(2). (s. NR 439.04(1)(d), Wis. Adm. Code)

(7) Each month the permittee shall calculate the total emissions of *each hazardous air pollutant* from the facility regulated by the Act as follows:[5]

$$E_x = (1\ \text{ton}/2000\ \text{lbs}) \times \{[(U_1 \times W_1 \times H_1) + (U_2 \times W_2 \times H_2) + \ldots + (U_n \times W_n \times H_n)] - [(S_1 \times I_1) + (S_2 \times I_2) + \ldots + (S_m \times I_m)]\}$$

where:

E_x is the monthly emissions of each hazardous air pollutant regulated by the Act (tons/month);

x identifies each HAP emitted from the facility

U is the monthly usage of each ink, coating, solvent, or other HAP containing material used during the month (gallons/month);

W is the density of each ink, coating, solvent, or other HAP containing material used during the month (pounds/gallon)

H is the HAP content of each ink, coating, solvent, or other HAP containing material used during the month expressed as a weight fraction (*i.e.* if a material is 25% HAP by weight H would be 0.25);

n identifies each ink, coating, solvent or other HAP containing material used during the month;

S is the amount of each spent ink, coating, solvent or other HAP containing material recovered and shipped off site each month (gallons/month);

I is the HAP content of each spent ink, coating, solvent or other HAP containing material recovered and shipped off site each month in pounds per gallon;

m identifies each spent ink, coating, solvent or other HAP containing material recovered and shipped off site during the month. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(8) To demonstrate compliance with condition I.A.2.a.(1), the permittee shall calculate the emissions of each hazardous air pollutant regulated by the Act over each 12 consecutive month period by summing the monthly emissions of each hazardous air pollutant regulated by the Clean Air Act (the Act) as calculated in I.A.2.b.(1) for each consecutive 12-month period. This calculation shall be performed within 20 calendar days of the end of each month for the previous 12 consecutive month period. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(9) Each month the permittee shall calculate the *total* emissions of hazardous air pollutants regulated by the Act as follows:

$$E_{hap} = E_x$$

where:

[5] This calculation shall be performed for each hazardous air pollutant regulated by the Act that is emitted from the facility.

E_{hap} is the monthly total emissions of all hazardous air pollutants regulated by the Act that are emitted by the facility (tons/month);

E_x is the monthly emissions of each hazardous air pollutant regulated by the Act (tons/month) as calculated in I.A.2.b.(1); x identifies each HAP emitted from the facility. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(10) To demonstrate compliance with condition I.A.2.a.(2), the permittee shall calculate the total emissions of *all* hazardous air pollutants regulated by the Act over each 12 consecutive month period by summing the monthly emissions of all hazardous air pollutants regulated by the Act as calculated in I.A.2.b.(3) for each consecutive 12-month period. This calculation shall be performed within 15 calendar days of the end of each month for the previous 12 consecutive month period. (s. NR 407.09(4)(a)1., Wis. Adm. Code)

(11) The permittee shall use coating manufacturer's formulation data to determine the HAP content (Hn) of the inks, coatings, solvents or other HAP containing materials used. (s. NR 439.04(1)(d), Wis. Adm. Code)

(12) The permittee shall analyze the spent ink, coating, solvent and other HAP containing material recovered and shipped off site to determine the HAP content (H) no less than: (a) each time there is a substantial change to materials or process operations that may affect the characteristics of the waste stream; or (b) quarterly, whichever is more frequent. (s. NR 439.04(1)(d), Wis. Adm. Code)

(13) The permittee shall keep records of the following for each ink, coating, solvent, or other HAP containing material used at the facility:

(a) A unique name or identification number; and

(b) The weight fraction of each HAP contained in the material (H_n). (s. NR 439.04(1)(d), Wis. Adm. Code)

(14) The permittee shall keep monthly records of:

(a) The amount of each ink, coating, solvent, or other HAP containing material used in gallons per month (U_n);

(b) The density of each ink, coating, solvent, or other HAP containing material used in pounds per gallon (W_n);

(c) The amount of spent ink, coating, solvent, or other HAP containing material recovered and shipped off site in gallons per month (S_m);

(d) The amount of each HAP contained in each spent ink, coating, solvent or other HAP containing material recovered and shipped off site in pounds per gallon (I_m);

(e) The facility total monthly emissions of each HAP in tons per month (E_x), as calculated in I.A.2.b.(1);

(f) The total monthly HAP emissions from the facility in tons per month (E_{hap}), as calculated in I.A.2.b.(3);

(g) The facility total emissions of each HAP in tons per year as calculated in I.A.2.b.(2).

(h) The total HAP emissions from the facility in tons per year as calculated in I.A.2.b.(4). (s. NR 439.04(1)(d), Wis. Adm. Code)

(15) Report actual facility wide volatile organic compound and hazardous air pollutant emissions as follows:

(a) The permittee shall submit a report summarizing the actual, facility wide volatile organic compound and hazardous air pollutant emissions for each consecutive 12-month period as calculated in conditions I.A.1.b.(2) and I.A.2.b.(2) and (4), every 6 months.

(b) The period addressed by the report shall be the 6 month period starting on the date the Cooperative Agreement is signed or other date agreed upon and approved by WDNR, EPA and the permittee, and each subsequent 6 month period thereafter.

(c) A copy of the report shall be submitted to the WDNR (Marty Sellers, Air Management Engineer, Department of Natural Resources, 3550 Mormon Coulee Road, La Crosse, WI 54601) and the U.S. EPA (Steve Rothblatt, Branch Chief, Air Program Branch, U.S. EPA, 77 W. Jackson Blvd., Mailcode: (AR–18J), Chicago, IL 60604) within 20 days following the end of the reporting period.

(d) If the report shows the actual facility wide volatile organic compound or hazardous air pollutant emissions have exceeded 50 percent of the allowable limitations outlined in conditions I.A.1.a and I.A.2.a.(1) and (2), the permittee shall provide an explanation why emissions reached the levels that they did and how they intend to ensure emissions will not exceed the allowable limitations outlined in conditions I.A.1.a. and I.A.2.a.(1) and (2). (s. NR 439.03(1)(a), Wis. Adm. Code)

Administrative Review

The EPA is publishing this SIP revision approval without prior proposal, because EPA views this as a noncontroversial revision and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the SIP revision should adverse written comments be filed. The approval of this SIP revision will be effective without further notice unless EPA receives relevant adverse written comments by February 24, 2003. Should EPA receive such comment, we will publish a final rule informing the public that this action will not take effect. Any parties interested in commenting on this action should do so at this time. If we do not receive comments, this action will be effective on March 25, 2003.

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. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This 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 or 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 an unfunded mandate nor does it significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule does not have tribal implications, because it will not have a substantial direct effect on one or more Indian tribes, or on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications, because it does not have substantial direct effects on the states, or the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act. Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19855, April 23, 1997), applies to any rule that is both economically significant, as defined under Executive Order 12866, and concerns an environmental health

or safety risk that EPA has reason to believe may have a disproportionate effect on children. This rule is not subject to Executive Order 13045 because it is not economically significant.

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTA), 15 U.S.C. 272 note, requires federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impracticable. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a SIP submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus standards in place of a SIP submission that otherwise satisfies the provisions of the Act. Therefore, the requirements of section 12(d) of the NTTA 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.*).

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business 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 the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the United States Senate, the United States 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 Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 25, 2003. 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 late in proceedings to enforce its requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Hazardous air pollutants, Volatile organic compounds.

Dated: October 24, 2002.

Bharat Mathur,

Acting Regional Administrator, Region 5.

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 YY—Wisconsin

2. Section 52.2570 is amended by adding paragraph (c)(107) to read as follows:

§ 52.2570 Identification of plan.

* * * * *

(c) * * *

(107) On June 12, 2002, the Wisconsin Department of Natural Resources submitted a site specific revision to its SIP for emissions from Northern Engraving Corporation's Holmen and Sparta facilities in the form of a Environmental Cooperative Agreement for incorporation into the federally enforceable State Implementation Plan. It consists of portions of the Environmental Cooperative Agreement which supersede portions of rules in the State Implementation Plan. The Cooperative Agreement establishes an exemption for pre-construction permitting activities for certain physical changes or changes in the method of operation at the Northern Engraving Corporation's Holmen and Sparta facilities.

(i) Incorporation by reference.

(A) The following provisions of the Environmental Cooperative Agreement between Northern Engraving Corporation (NEC) and the Wisconsin Department of Natural Resources signed on June 10, 2002: Section XI of the Environmental Cooperative Agreement (Operational Flexibility and Variances) and Part IA. of Appendix C.3: Specific Permit Conditions under the Environmental Cooperative Agreement for NEC's Sparta facility.

[FR Doc. 03–1516 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[DC039–2030; MD073–3101; VA090–5063; FRL–7441–9]

Determination of Nonattainment as of November 15, 1999, and Reclassification of the Metropolitan Washington, DC Ozone Nonattainment Area; District of Columbia, Maryland, Virginia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to issue a determination that the Metropolitan Washington, D.C. serious ozone nonattainment area (hereinafter referred to as the Washington area) did not attain the 1-hour ozone national ambient air quality standard (NAAQS) by the November 15, 1999 Clean Air Act (CAA) deadline for serious ozone nonattainment areas. As a result, the Washington area is reclassified by operation of law as a severe ozone nonattainment area on the effective date of this rule. The District of Columbia, the State of Maryland and the Commonwealth of Virginia each must submit by March 1, 2004, a State Implementation Plan (SIP) revision for the Washington area that meets the severe area ozone nonattainment area requirements of CAA section 182(d). Finally, EPA is adjusting the dates by which the area must achieve a nine (9) percent reduction in ozone precursor emissions to meet the 2002 rate-of-progress (ROP) requirement and adjusting contingency measure requirements as this relates to the 2002 ROP milestone. In an Order entered on December 18, 2002, the United States District Court for the District of Columbia directed EPA to publish a final action in the **Federal Register** determining whether the Washington area had attained the applicable ozone standard under the CAA and any reclassification of the area required as a result of this determination. This final determination and this notice are in direct response to and comply with the Court's order.

DATES: This final rule is effective on March 25, 2003.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Christopher Cripps, (215) 814–2179, or by e-mail at *Cripps.Christopher @epa.gov.*

SUPPLEMENTARY INFORMATION: The use of ''we,'' ''us,'' or ''our'' in this document refers to EPA.

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I. What Is the Background for This Rule?

A. When Did EPA Propose to Reclassify the Washington Area?

On November 13, 2002, EPA proposed to find that the Washington serious ozone nonattainment area did not attain the 1-hour ozone NAAQS by November 15, 1999, the attainment deadline for serious ozone nonattainment areas under CAA section 181(a). *See* 67 FR 68805. The proposed finding was based upon ambient air quality data from the years 1997, 1998, 1999. These data showed that the 1-hour ozone NAAQS of 0.12 parts per million (ppm) had been exceeded on an average of more than one day per year over this three-year period and that the area did not qualify for an attainment date extension under section 181(a)(5). EPA also proposed that the appropriate reclassification of the area was to severe ozone nonattainment.

B. What Is the Washington Ozone Nonattainment Area?

For the purposes of this final rule, the Washington ozone nonattainment area (the Washington area) consists of: the District of Columbia; Calvert, Charles, Frederick, and Montgomery, Prince Georges counties in Maryland; and, the counties of Arlington, Fairfax, Loudoun, Prince William and Stafford and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park in Virginia. *See* 40 CFR 81.309, 40 CFR 81.321 and 40 CFR 81.347.

C. What Is a SIP?

Section 110 of the CAA requires states to develop air pollution regulations and control strategies to ensure that state air quality meet the NAAQS established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each Federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive. They may contain state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

D. What Is the NAAQS for Ozone?

The NAAQS for ozone is expressed in two forms which are referred to as the 1-hour and 8-hour standards. Table 1 summarizes the ozone standards.

Standard	Value	Type	Method of compliance
1-hour	0.12 ppm	Primary and Secondary	Must not be exceeded, on average, more than one day per year over any three-year period at any monitor within an area.
8-hour annual	0.08 ppm	Primary and Secondary	The average of the fourth highest daily maximum 8-hour average ozone concentration measured at each monitor over any three-year period.

(Primary standards are designed to protect public health and secondary standards are designed to protect public welfare and the environment.)

The 1-hour ozone standard of 0.12 parts per million (ppm) was promulgated in 1979. The 1-hour ozone standard continues to apply to the Washington area, and it is the classification of the Washington area with respect to the 1-hour ozone standard that is addressed in this document.

E. How Did EPA Apply the CAA Provisions Regarding Determinations of Nonattainment and Reclassifications to the Washington Area?

On November 13, 2002, EPA proposed its finding that the Washington area did not attain the 1-hour ozone standard by the applicable date (67 FR 68805). In that notice of proposed rulemaking we discussed how we believed the provisions of section 181(b)(2), the relevant sections of the CAA regarding determinations of attainment and reclassifications for failure to attain, would apply to the Washington area. *See* 67 FR at 68806 to 68808. The proposed finding was based upon ambient ozone concentration data for the period 1997 through 1999, from the monitoring sites in the Washington area, several of which recorded an average of more than one exceedance per day per year.

Section 181(b)(2)(A) of the Clean Air Act requires that when EPA determines that an area has not attained the standard by its statutorily required date the area shall be reclassified by operation of law to the higher of—

(1) The next higher classification for the area, or

(2) The classification applicable to the area's design value as determined at the time EPA publishes its notice that the area failed to attain.

Even if a serious area's design value at the time of reclassification is lower than the design value for serious areas that serious area cannot be reclassified to a lower classification because the minimum statutory classification resulting from a failure to attain is severe.

The air quality data upon which we made the proposed finding of failure to attain the ozone NAAQS were available for comment in our November 13, 2002, notice of proposed rulemaking. For a listing of the average number of days when ambient ozone concentrations exceeded the one-hour ozone standard, *See* 67 FR at 68807–68808 (November 13, 2002). We received no adverse comments pertaining to that air quality data and the proposed determination of noattainment.

EPA has determined that the relevant air quality data for the period of 1997 through 1999, inclusive, for the Washington area shows that the Washington area contained at least one monitor with an average annual number of expected exceedances that was greater than the 1.0 allowed by the 1-hour ozone NAAQS. Although currently classified as a ''serious'' nonattainment area, if the Washington area were being

classified for the first time today, the classification applicable to the area's design value would be ''marginal.'' However, section 181(b)(2)(A)(1) requires that an area be reclassified to the higher of its current design value or the next higher classification (with the exception that no area can reclassified to ''extreme''). ''Severe,'' not ''marginal,'' is the next higher nonattainment classification from ''serious'' under CAA. Therefore, we make the determination pursuant to section 181(b)(2)(B) of the CAA that the Washington area did not attain the one-hour ozone standard by the November 15, 1999, attainment date, and that the area is reclassified by operation of law to severe nonattainment on the effective date of this rule.

F. Why Is This Action Necessary?

On November 13, 2002, the Sierra Club filed a complaint in the United States District Court for the District of Columbia against EPA (*Sierra Club* v. *Whitman,* No. 1:02CV02235(JR)) regarding, among other things, the attainment status and classification of the Washington area. On December 18, 2002, the United States District Court for the District of Columbia issued an order directing EPA to publish, by January 27, 2003, a determination of whether the Washington area had attained the applicable ozone standard under the CAA. The Court also ordered EPA to publish in the **Federal Register** a notice of a final action reflecting both this determination and any reclassification of the area required as a result of the determination. Our final determination and this notice comply with the Court's Order.

II. What Does This Action Do?

In this action, EPA is issuing a final determination that the Washington area did not attain the 1-hour ozone NAAQS by November 15, 1999, as prescribed in section 181 of the CAA, in fulfilling our nondiscretionary duty pursuant to the CAA. As a result of this final determination, the Washington area is reclassified by operation of law to severe ozone nonattainment pursuant to section 181(b)(2) of the CAA. In addition, this action sets the dates by which the District of Columbia (the District), Maryland and Virginia (collectively referred to as ''the States'') each must submit SIP revisions addressing the CAA's pollution control requirements for severe ozone nonattainment areas (the ''severe area SIP'') and to attain the 1-hour NAAQS for ozone. The required post-1999 ROP nine percent reduction originally was required by November 15, 2002 under the CAA. However, that date has elapsed. Therefore, in this action EPA is allowing the District, Maryland and Virginia to demonstrate that the first required post-1999 nine percent ROP is achieved as expeditiously as practicable after November 15, 2002, but in any case no later than November 15, 2005. EPA is allowing the District, Maryland and Virginia to key contingency measures for the 2002 ROP milestone to this new date.[1]

III. What Public Comments Were Received and What are EPA's Responses?

In the November 13, 2002, notice of proposed rulemaking (67 FR 68805) for this action, EPA proposed: (1) To find that the Metropolitan Washington, DC serious ozone nonattainment area has failed to attain the one-hour ozone NAAQS by November 15, 1999, and, as a consequence, the Washington area would be reclassified as a severe nonattainment area; (2) to require the District of Columbia, the State of Maryland and the Commonwealth of Virginia to submit revisions to their State Implementation Plan (SIP) that adopt the severe area requirements by the earlier of one year after the effective date of a final action on the attainment determination or March 1, 2004; and (3) to allow the District, Maryland and Virginia to adjust the dates by which the area must achieve a nine percent reduction in ozone precursor emissions to meet the 2002 rate-of-progress requirement to a date as expeditiously as practicable (but in no case any later than November 15, 2005), and to adjust the contingency measure requirement as this relates to the 2002 rate-of-progress requirement accordingly.

We solicited public comments on these issues discussed in the notice of proposed rulemaking as well as other relevant matters. We received comment letters from Earth Justice Legal Defense Fund (on behalf of the Sierra Club), the Virginia Department of Transportation, Dominion Energy and three residents of the Washington area.

In this document, EPA is responding to adverse comments that are germane to this final action and which were submitted in response to the November 13, 2002, notice of proposed rulemaking (67 FR 68805).

EPA received no adverse comments pertaining to the data used for our nonattainment determination, and therefore we are making the determination that Washington did not attain by its attainment deadline.

A. Finding of Failure to Attain and Reclassification to Severe

Summary of Comments in Support of EPA's Proposed Action

EPA received comments supporting the determination of nonattainment and the change in the classification from serious to severe. One resident of the District expressed concern about personal health effects of breathing air in the District which the commenter believes is not as clean as in more rural areas. Another commenter stated support for the proposed finding of failure to attain and stated concurrence that the resulting reclassification by operation of law should result in a severe classification.

Comments Adverse to EPA's Proposed Action

Comment #1: We received one comment that stated the major reason that the Washington, area is being reclassified from serious to severe is because of transport from outside the area. The commenter claimed that other States and industries in the ''Ohio Valley'' have not reduced emissions soon enough to enable the Washington area attain by 1999.

Response #1: While EPA agrees that the Washington area is significantly affected by transport from outside the area, the U.S. Court of Appeals for the D.C. Circuit ruled on July 2, 2002 that EPA is precluded from extending the Washington area's attainment date unless the extension qualifies under CAA section 181(a)(5) or it involves reclassification to a higher classification. With respect to attainment date extensions, the D.C. Circuit also ruled that the plain language of the Clean Air Act ''sets a deadline without an exception for setbacks owing to ozone transport.'' Therefore, the Court held that EPA is without authority to extend the attainment deadline for the Washington area unless we also reclassify the area as a severe nonattainment area. *See Sierra Club* v. *Whitman,* 294 F.3d 155, 163 (D.C. Cir. 2002).

EPA is issuing a final finding that the Washington area failed to attain the 1-hour ozone NAAQS and is reclassified by operation of law to severe nonattainment.

[1] The severe area ROP plan will also have to provide for the second increment of post-1999 ROP for the period 2002 to 2005 and thus must achieve a minimum of 18 percent emission reduction from base line emissions by November 15, 2005.

B. Severe Area SIP Revision Submittal Schedule

Comments Supporting a Shorter Schedule and on Application of Section (i)

One commenter submitted extensive comments in opposition to the proposed schedule for submittal of the severe area SIP.

This commenter claims EPA's use of section 182(i) is arbitrary and capricious and contrary to law. The commenter notes that the CAA set deadlines for SIP submittals for serious and severe areas in CAA sections 182(c)(2) and (d). The commenter claims those deadlines are not subject to adjustment and have long passed.

This commenter noted the following deadlines as examples:

(1) November 15, 1992: ''VMT offset'' SIP due under CAA section 182(d)(1).

(2) November 15, 1992: NSR program mandated by CAA sections 172(c)(5) and 173 including the lower stationary source major source thresholds for severe areas.

(3) November 15, 1994: for the attainment demonstration due under CAA sections 182(c)(2) and (d).

(4) December 31, 2000: SIP provision due under CAA section 182(d)(3) to fulfill the requirements of section 185.

The commenter claims that section 182(i) requires areas to met the deadlines of sections 182(b)–(d) and allows EPA to adjust those deadlines only to the extent necessary or appropriate to assure consistency among the required submissions. The commenter claims that EPA has not provided a rationale why the proposed schedule is necessary and appropriate and therefore EPA must make immediate ''findings of incompleteness'' under section 110(k)(1)(B).

The commenter further claims the proposed schedule has other problems in that the schedule runs afoul of the statutory attainment and ROP deadlines:

(1) The 2002 ROP plan will be due 16 months after the 2002 milestone date,

(2) The first potential sanction could only be imposed by August-September 2005 around 34 months after the 2002 ROP milestone date and around two months before the attainment date.

(3) The second potential sanction and the mandate for any needed Federal Implementation Plan would not come due until after the attainment deadline of November 15, 2005. Thus the commenter concludes the proposed schedule also is contrary to the CAA in that the plans would not be submitted and implemented prior to ROP and attainment deadlines.

With regard to the 2002 milestone, the commenter further claims that the Courts have already said that the Washington area SIP ROP plan is deficient and must be disapproved because the plan fails to provide an annual average of three percent ROP after November 15, 1999. The commenter's theory is that section 182(c)(2)(B) mandates post-1999 ROP even for serious areas and that the submittal deadline for this SIP is November 15, 1994. Under this theory the commenter concludes the EPA has no authority to extend the deadline for submittal of the ROP plans since the statutory due date of November 15, 1994 is past.

The same commenter further asserts that even if EPA could lawfully extend the submittal date (although the commenter disputes this very point) the standard for submission should be ''as soon as possible.'' The commenter submitted a schedule recently developed by the Metropolitan Washington Air Quality Committee (MWAQC) [2] that the commenter interprets as a demonstration that the air quality planning agencies could develop the entire severe area SIP by July 2003. The commenter maintains that EPA must set the submittal date to no later than the date the air quality planning agencies maintain is necessary to finish the task.

One other commenter urged EPA to be proactive in enforcing the severe area requirements and urged EPA to enable an expeditious switch from the MOBILE5 to MOBILE 6.

Response to Comments Supporting a Shorter Schedule and on Application of Section 182(i)

Response to Comment on Section 182(i): EPA's exercise of discretion under section 182(i) to adjust the submission deadlines for the severe area requirements that become applicable to the D.C. area for the first time upon the effective date of the area's reclassification is not arbitrary or capricious, and is in keeping with the terms and purpose of the statute. Section 182(i) states that the Administrator may adjust applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions of new requirements applicable to an area which has been reclassified. Where a submission date has passed and is therefore impossible to meet, EPA has concluded that the Administrator may establish a later date. EPA has applied this interpretation in its prior reclassification rulemaking actions. *See* Santa Barbara, California, (62 FR 65025, December 10, 1997); Phoenix, Arizona (62 FR 60001, November 6, 1997); and Dallas-Fort Worth, Texas (63 FR 8128, February 18, 1998). The structure of the Clean Air Act itself reinforces this interpretation. Under the Act, the original dates for submissions for areas initially classified as serious, severe, and extreme areas was 1994. The attainment date for serious areas is 1999. Thus the Act does not require EPA to make a determination of whether or not a serious area met its 1999 attainment deadline until more than five years after the original submission date for areas originally classified as severe. Since the original 1992, 1994 and 2000 submission dates have elapsed, it is impossible for EPA to establish any of these as the submission deadline for a newly reclassified area.

EPA has determined that in light of the fact that the original submission dates for severe areas have elapsed prior to the time that we issued the proposed reclassification rulemaking for the Washington area, it is a reasonable exercise of EPA's discretion to adjust the applicable submission deadlines in order to ensure consistency among the new requirements. Because it is impossible for the state to meet long-expired deadlines, EPA must set new deadlines that will ensure consistency of submissions for requirements that the state is only being notified that it must meet. This is entirely in keeping with the discretion that Congress accorded EPA in section 182(i), and with EPA's prior reclassification rulemakings making appropriate adjustments to submission deadlines. Because the States must now meet newly imposed requirements such as post-1999 ROP and additional severe area control requirements, EPA must set prospective submission dates, and has authority under section 182(i) to make these dates consistent.

To interpret the Clean Air Act as the commenter suggests would give the reclassification retroactive effect by holding the States in default of their submission obligations before the events necessary to trigger that obligation (reclassification) has occurred. Until EPA acts to reclassify an area, the states are under no obligation to make the required submissions. To subject them to a lapsed deadline after reclassification would be patently unfair and contrary to the statute's intent. Giving the submission deadlines

[2] The commenter identified this agency as the Metropolitan Washington Council of Governments (MWCOG).

retroactive effect would also be inconsistent with the Administrative Procedure Act, 5 U.S.C. 553(d), which requires that before a rule takes effect, persons affected will have advance notice of its requirements. A failure to meet an obligation, especially one accompanied by sanctions, cannot occur in advance of the imposition of that obligation. The obligation to submit requirements to meet the severe area classification did not exist for the Washington area prior to the final action that reclassifies the area. Giving retroactive effect to the old SIP submission deadlines would also preclude EPA from exercising the discretion with respect to setting the deadlines for these submissions that is specifically afforded by section 182(i).

In *Sierra Club* v. *Whitman,* 130 F. Supp.2d 78 (D.D.C. 2001), *affirmed,* 285 F.3d 63 (D.C. Cir. 2002), a case involving the reclassification of the St. Louis nonattainment area, the District Court refused to interpret the reclassification provisions as authorizing relief that would treat submission deadlines as having lapsed prior to EPA having issued a reclassification rulemaking. The court stated that such an interpretation ''could 'create * * * an injustice at the hands of the court itself.' '' 130 F. Supp.2d at 94. Such relief ''could throw the (area) into extreme noncompliance.'' *Id.* The court refused to impose such relief when it ''could effectively penalize the state and local entities that are required to comply with EPA findings.'' *Id.* In the St. Louis case, the Sierra Club demanded not only retroactive reclassification, but also demanded that the district court declare that ''the State of Missouri has failed to file a SIP revision that comports with the requirements of section 7511a(c) by the statutory deadline of May 15, 1998,'' *id.* at 87, a date that had long since passed. The district court refused to do so, recognizing that this would unfairly penalize the States, which are entitled to rely on EPA's actions in anticipating the burdens that will be imposed pursuant to the CAA. Imposition of sanctions would also have unfair adverse consequences for emissions sources.

The D.C. Circuit upheld the District court's ruling. ''In any event, what Sierra Club sought—to have the effective date of EPA's court-ordered determination converted to the date the statute envisioned, rather than the actual date of EPA's action—was a form of relief the district court quite properly rejected.'' *Sierra Club* v. *Whitman* 285 F.3d 63, 68 (D.C. Cir. 2002). The D.C. Circuit continued: ''Although EPA failed to make the nonattainment determination within the statutory time frame, Sierra Club's proposed solution only makes the situation worse. Retroactive relief would likely impose large costs on the States, which would face fines and suits for not implementing air pollution prevention plans in 1997, even though they were not on notice at the time.'' *Id. See also NRDC* v. *EPA,* 22 F.3d 1125 (D.C. Cir. 1994).

EPA believes that it has provided an adequate rationale for its exercise of discretion in setting the applicable submission deadlines, and that it would be unreasonable and inappropriate to make the ''immediate findings of incompleteness'' that the commenter suggests.

Response to Comment on ROP Submissions

The Commenter's contention that the ROP submissions are inadequate also ignores the fact that reclassification is occurring in 2003, and thus it is impossible for the State to meet the 2002 milestone date. See the discussion in the preceding paragraphs regarding the impossibility of meeting deadlines that have already passed, and the ROP discussion in the following paragraphs.

The commenter claims that ''the rate of progress plans for the Washington area are already deficient because they fail to provide for the post-1999 progress mandated by section182(c)(2)(B). *Sierra Club* v. *Whitman,* 294 F.2d 155, 163 (D.C. Cir. 2002).'' The commenter claims plans to fulfill the post-1999 ROP obligation we due to EPA by November 15, 1994, and that because such plans were never submitted, EPA must therefore ''disapprove those plans immediately.''

With respect to the claim that EPA must disapprove these previously submitted ROP plans, this claim is not relevant to the proposed action, which was for the reclassification of the Washington area concurrent with the establishment of a reasonable deadline for submitting SIP revisions. EPA will be taking a separate action on the submitted ROP plans, which will address their approvability.

With respect to the claim that the area was required to submit to EPA a plan to fulfill post-1999 ROP by November 15, 1994, the commenter ignores the context of the Circuit Court's decision with respect to post-1999 ROP obligations. The Circuit Court was merely agreeing with an observation made by the plaintiff that ''*with an attainment date in 2005,* 'the rate of progress plan for the Washington area had to demonstrate a 9% reduction in emissions from 1996 to 1999, another 9% from 1999 to 2002, and another 9% from 2002 to 2005''' (emphasis added).

However, the Circuit Court vacated as contrary to the statute EPA's approval of a 2005 attainment date for the Washington area to attain as serious area. 294 F.2d at 164. Consequently, until the effective date of final action to reclassify the Washington area as a severe nonattainment area with an attainment date of November 15, 2005, the attainment date for the Washington area remained the November 15, 1999 date for serious areas. Indeed, it is the failure of the Washington area to attain the one-hour ozone NAAQS by November 15, 1999 that results in the area being reclassified as a severe area.

As a serious area with a lapsed attainment date of November 15, 1999, the Washington area had no legal obligation to provide for post-1999 ROP. As noted by the Circuit Court, only an area with an attainment date of 2005 has a legal obligation to provide for post-1999 ROP. The Washington area will not have an attainment date of 2005 until the effective date of its reclassification as a severe area. A serious area has an obligation to provide for ROP until its attainment date, which is 1999. *See* section 182(c)(2)(B) and section 181(a)(1). Not until it is reclassified to severe does an area have a later attainment date and a consequent obligation to provide for ROP until that later attainment date (2005 in the case of the Washington area). *See* section 182(d). As explained elsewhere in this section of this document in the responses regarding application of section 182(i), the Administrative Procedure Act requires that new obligations, such as the one to demonstrate post-1999 ROP for an area reclassified to severe nonattainment, cannot be imposed retroactively.

Response to Comment on Findings of Incompleteness

One commenter suggests that because EPA has not provided a rationale why the proposed schedule is necessary and appropriate the SIP is past due (under the schedule provisions of section 182(b)–(d)) and thus EPA must make immediate ''findings of incompleteness'' under section 110(k)(1)(B). As discussed in previous paragraphs of this document, EPA disagrees with the commenter that section 182(i) prohibits EPA from providing the state with time to submit a SIP consistent with its reclassification from serious to severe. As provided in the preceding paragraphs, EPA has concluded that it is reasonable and appropriate to provide the state until March 1, 2004, to submit

a SIP based on its reclassification. Thus, there is no SIP due yet and there is no basis to find that the state failed to submit a complete SIP. To the extent the commenter is suggesting that EPA determine the area's serious area SIP to be incomplete, EPA notes that the serious area SIP revisions for which EPA has not issued a final action were deemed complete or deemed complete by operation of law under CAA section 110(k)(1)(B). These serious area SIP revisions and their submission dates are listed in the following table.

TABLE 2.–SUBMITTAL DATES OF SERIOUS AREA SIP REVISIONS

[Post-1996 ROP Plans and Contingency Measure Plans]

	District of Columbia	Maryland	Virginia
Initial submittal dates	November 10, 1997	December 24, 1997	December 19, 1997.
Amendment dates	May 25, 1999	May 20, 1999	May 25, 1999.
Attainment Demonstrations			
Initial submittal dates	April 24, 1998	April 29, 1998	April 29, 1998.
Amendment dates	October 27, 1998	August 17, 1998	August 18, 1998.
Supplemental dates	February 16, 2000	February 14, 2000 (MD SIP No. 00–01)	February 9, 2000.
Supplemental dates	March 22, 2000	March 31, 2000 (MD SIP No. 00–02)	March 31, 2000.

All the attainment demonstration SIP revisions were deemed complete by operation of law under CAA section 110(k)(1)(B) six-months after the dates listed in the preceding table. Therefore, the latest of these revisions related to the attainment demonstration, those submitted in March 2000, were complete by operation of law on or prior to October 1, 2000.

On November 3, 1997, the District submitted the Post-1996 plan to EPA as a proposed revision to the District's SIP. On December 10, 1997, EPA determined that the Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). On May 25, 1999, the District submitted a revised Post-1996 plan document to EPA as a revision to the District's SIP. On July 14, 1999, EPA determined that this revised Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V.

On December 24, 1997, Maryland submitted the Post-1996 plan to EPA as a proposed revision to Maryland's SIP. On January 14, 1998, EPA determined that the Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V. On May 20, 1999, Maryland submitted a revised Post-1996 plan document to EPA as a revision to Maryland's SIP. On July 14, 1999, EPA determined that this revised Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V.

On December 19, 1997, Virginia submitted the Post-1996 plan to EPA as a proposed revision to Virginia's SIP. On January 12, 1998, EPA determined that the Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V (1991). On May 25, 1999, Virginia submitted a revised 1999 Post-1996 plan document to EPA as a revision to Virginia's SIP. On July 26, 1999, EPA determined that this revised Post-1996 plan fulfilled the completeness criteria set out at 40 CFR part 51, appendix V.

EPA believes that it has provided an adequate rationale for its exercise of discretion in setting the applicable submission deadlines, and that it would be unreasonable, inappropriate and contrary with applicable law to make the ''immediate findings of incompleteness'' that the commenter suggests.

Response to Comment That July 2003 Should Be the Submittal Date

One commenter submitted a schedule that was presented to the Transportation Planning Board (TPB) at their December 18, 2002, meeting. EPA does not disagree that this schedule was developed on December 4, 2002, and adopted by the Metropolitan Washington Air Quality Committee (MWAQC). However, this schedule clearly shows three parallel tracks of activities: the first is the ''SIP schedule''; the second is ''State Action Deadlines''; and the third is ''TPB Conformity''. The schedule says that in January 2003 the preliminary shortfall analysis for 2005 will be completed. The same document says that in February 2003 the States will provide schedules for Title I modifications.

The severe area SIP has many elements. One is a ROP plan for the post-1999 ROP milestone years to include conformity budgets, emission target levels determinations, and future year emissions levels projections. Another is revisions to the area's mobile source emissions estimates for the base year and previously submitted 2005 budgets using MOBILE6. Historically, the MWAQC develops these elements of the SIP, ensures inter-State coordination and ensures that appropriate consultation regarding the mobile source emissions budgets with the transportation planning agencies occurs. However, it is the States, not MWAQC, that must adopt the MWAQC plans for inclusion in each State's SIP. Historically, the States have had to adopt control measure regulations to support the MWAQC air quality plans and meet CAA requirements for nonattainment areas.

The severe area SIP elements that will require action by the District, Virginia and Maryland include any needed changes to each jurisdiction's new source review permitting rules to incorporate the severe area offset ratios and major source thresholds or to lower reasonable available control technology major source thresholds. Other examples could include adoption of regulations to address any post-1999 ROP plan reduction needs not provided by the current control strategies in the SIPs and to address contingency measure requirements.

The District of Columbia, Virginia and Maryland each have written to EPA indicating that they support the date of March 1, 2004, to complete the total severe area SIP package. These States have clarified that MWAQC's use of the term ''severe area SIP'' does not mean the total package.

The Maryland Department of the Environment (MDE) understands that MWAQC's plan is to finalize and forward a recommended SIP revision to the States in July 2003. MDE indicates that MDE will need to complete additional tasks after the MWAQC completes its work on the severe area SIP for the Washington area. These tasks

include promulgating the new mandatory Title I provisions like New Source Review, contingency measures and any shortfall measures that result from the MWAQC process. Maryland has already started to draft regulations for some of these SIP elements, but believes that it will take until March 1, 2004 to finalize many of the rules that will need to be included as part of the final SIP submittal.

The District of Columbia Department of Health, Division of Air Quality (DC DAQ), points out that the schedule adopted by the MWAQC is very aggressive and establishes milestones and actions for which MWAQC is responsible, but it does not include all the steps involved in developing a complete SIP.

DC DAQ notes it can not complete by July 2003 either the regulatory process for the required Title I NSR changes or the NO_X RACT determinations for sources that emit between 25 and 50 tons per year by July 2003. The DC DAQ notes it cannot complete these in less than six months and notes the normal schedule for adoption of rules is ten months. The DC DAQ has informed us that any measures identified as RACM will require time beyond July 2003 for the development of implementation plans and schedules.

The Virginia Department of Environmental Quality (DEQ) points out that the schedule adopted by the MWAQC is very aggressive and establishes milestones and actions for which MWAQC is responsible, but it does not include all the steps involved in developing a complete SIP.

DEQ notes it can not complete by 2004 either the regulatory process for the additional rulemakings required or the NO_X RACT determinations for sources that emit between 25 and 50 tons per year before March 2004. DEQ is currently working on both of these tasks. DEQ has informed us that any measures identified as RACM will require time beyond July for the development of implementation plans and schedules.

Given that the contingency measures or other necessary measures (e.g., any remaining reasonably available control measures or measure needed to uncover a shortfall found by the ROP planning which is scheduled to be available only in January 2003) have not been selected (or even identified), EPA does not believe that any State could adopt new measures between January and July 2003. Nothing from the States indicates otherwise.

For the reasons set forth above, we cannot conclude from the information before us that the schedule provided by the one commenter reflects the intention that all three States would submit complete severe area SIP packages to EPA by July 2003. Indeed, three of the States have informed us that they could not meet, and have never intended or committed to meet, a July 2003 SIP submittal deadline.

Likewise, information received from the States provides no reason to extend the severe area SIP submittal date beyond what we proposed on November 13, 2002. We proposed a submittal date of one year after the effective date of a final reclassification to severe but not later than March 1, 2004. Because one year after the effective date of this action will be past March 1, 2004, we are setting a deadline for the submission of the severe area SIP as March 1, 2004.

Comments Supporting a Longer Schedule Than That Proposed

Two commenters asserted that one year to develop the severe area SIP is insufficient given the length of time required by one state's regulatory adoption process and the need to allow time to identify additional control measure needs to meet the severe area requirement. The first of these two commenters noted that one state needed 18 months to adopt control regulations while the second stated that the same state would require 18 to 24 months for this process. The first of these two commenters urged EPA to set the due date for submittal of the severe area SIP to 24 months. The second of these two commenters urged EPA to add at least six months to the proposed March 1, 2004, date found in the proposal or to allow enforceable commitments.

EPA's Response To Comment on Need for a Longer Schedule for Submission

EPA believes that the deadlines it has set for submission of the severe area requirements are consistent with the Clean Air Act and are adequate for the area to achieve compliance. EPA has discretion to adjust deadlines under section 182(i). EPA believes that a period up to eighteen months would be consistent with the Act, since under section 110(k)(5) the Clean Air Act SIP revision provision, states have up to 18 months to submit a SIP revision after receiving a SIP call notice.

Given that the States have indicated in this case that March 1, 2004, is not unreasonable, and we received no adverse comments from the states during the comment period indicating that they could not meet this deadline, EPA is setting a deadline for the submission of the severe area SIP as March 1, 2004.

C. Rate-of-Progress (ROP) and Contingency Measures for 2002

Comments in Support of Allowing the States To Adjust the 2002 Milestone

One commenter supported the ''expeditious'' standard as being appropriate. Another commenter agreed with EPA that the nine percent reduction should be achieved as soon as practicable after November 15, 2002.

Comments in Opposition To Allowing the States To Adjust the 2002 Milestone

One commenter stated that EPA cannot move the November 15, 2002, statutory deadline for the 2002 ROP reduction of nine percent between November 15, 1999, and November 15, 2002. The commenter claims that the ROP plan for the Washington area has to demonstrate a nine percent reduction in emissions between November 15, 1999, and November 15, 2002, (as well as nine percent between November 15, 1996, and November 15, 1999, and another nine percent between November 15, 2002, and November 15, 2005). The commenter claims that if the states cannot show a nine percent reduction between November 15, 1999 and November 15, 2002, then the states must implement the only alternative scheme allowed by statute, namely that of section 182(c)(2)(B)(ii).

The same commenter asserts that even if the statute were not explicit as to the ROP deadline, the proposed ''as expeditiously as practicable'' standard should be ''as soon as possible with every control measure.'' The commenter further asserts that the term ''practicable'' in ''as expeditiously as practicable'' is not defined in terms of what factors will go into the determination and thus could be used to nullify the statutory deadline.

This commenter further asserts that EPA does not have the statutory authority to move the 2002 ROP milestone date and thus there is no need for the contingency plan requirement to account for a date other than November 15, 2002.

Response: With respect to the assertion that EPA lacks authority to allow the States to demonstrate the first required post-1999 nine percent ROP, due under the statute by November 15, 2002, as expeditiously as practicable, EPA disagrees, in light of the fact that the statutory deadline has passed. It is impossible for the states to demonstrate any progress by a date that passed before the time the area became classified a severe area and thus first became subject to the requirement to demonstrate post-1999 ROP. EPA agrees that the Washington area must now

demonstrate such progress, but reasonably concludes that the states must have some time in which to actually develop and implement the measures to achieve such ROP. EPA has addressed similar issues on several occasions in the past when areas for various reasons have not timely submitted progress SIPs, and when the date for achieving progress had passed prior to EPA action on a progress SIP. EPA has routinely concluded in these circumstances that the area should demonstrate the required ROP as expeditiously as practicable once the statutory date for achieving such ROP had passed. *See, e.g.*, 65 FR 31485 (May 18, 2000), 63 FR 28898 (May 27, 1998), 62 FR 31343 (June 9, 1997). Even though, as the commenter points out, there is no provision in the statute expressly addressing the situation where an area has failed to timely submit a progress SIP, EPA must fill the statutory gap where such SIPs are submitted after the date for achieving progress, and EPA has reasonably done so in this case by following its past practice of requiring such SIPs to demonstrate ROP as expeditiously as practicable. Although no court has directly addressed the issue of the propriety of this ''as expeditious as practicable'' standard, courts have addressed other issues concerning ROP plans submitted after the statutory date for achieving ROP, which have demonstrated ROP as expeditiously as practicable, without expressing any concern with that standard. *See, e.g., Sierra Club* v. *EPA,* 252 F.3d 943 (8th Cir. 2001) (Court upheld calculation methods used in 15 percent ROP plan submitted three years after statutory date demonstrating achievement of ROP seven years after statutory date).

The commenter indicates that the only statutory provision allowing less than a nine percent reduction by 2002 is CAA section 182(c)(2)(B)(ii). However, the commenter misconstrues that section which provides for areas to demonstrate that they have adopted various feasible measures in exchange for achieving a less than nine percent reduction. Although this provision would remain available to the Washington area states should they be unable to demonstrate the required average annual three percent reduction after November 15, 1996, through the attainment date of November 15, 2005, EPA did not propose to allow the states to show less than the nine percent reduction. EPA merely acknowledged in the proposal that the statutory date for achieving the nine percent reduction had passed and that in such event the states should demonstrate the full nine percent reduction as expeditiously as practicable.

The commenter also objects to the observed stringency of the ''as expeditious as practicable'' standard, citing a case involving the 1987 attainment date in the 1977 version of the Clean Air Act, in which the court held that once an attainment date has passed an area must demonstrate attainment ''as soon as possible with every available control measure.'' *Delaney* v. *EPA,* 898 F.2d 687, 691 (9th Cir. 1990). However, that case was interpreting EPA's 1981 guidance on planning for post-1987 attainment, in which EPA had indicated that areas which could not attain by 1987 should identify all ''measures possible in a longer time frame that, together with the measures already evaluated, will result in attainment as quickly as possible after 1987.'' 46 FR 7186, 7188 (January 22, 1981). Subsequent to the *Delaney* opinion, EPA published a **Federal Register** notice in which it clarified that the agency never intended that its 1981 guidance be interpreted to require the imposition of draconian control measures, nor to require immediate attainment after 1987 if only such measures could produce it. 55 FR 38326 (September 17, 1990). To avoid future misinterpretation of this guidance, EPA then revoked those aspects of the 1981 guidance requiring the use of ''all possible measures'' after 1987. *Id.,* at 38327. The EPA instead concluded that Federal and State post-1987 planning should attain the standard ''as expeditiously as practicable,'' as required by section 172(a)(2). EPA concluded that the statute does not require measures that are absurd, unenforceable, or impracticable, and thus that, after 1987, EPA would equate its interpretation of the Ninth Circuit's standard in *Delaney* of attainment ''as soon as possible'' absent absurd, impossible, or unenforceable measures with the statutory test of attainment ''as expeditiously as practicable.'' *Id.* This is the interpretation EPA has consistently held since that time, as noted in the various **Federal Register** actions mentioned above where areas have missed statutory deadlines for attainment or ROP.

Moreover, EPA notes that one court, while finding *Delaney* not precisely on point for its purpose of fashioning a remedy in a citizen's enforcement action, nevertheless made some instructive observations on the relationship between the two standards. The Court noted that: ''[A]lthough the Delaney opinion utilized the 'as soon as possible' standard employed by EPA guidelines, it did not do so out of rejection of the 'practicable' standard or out of concern that the two standards differed. Rather it simply had no occasion to compare them. Indeed the Delaney court appeared to blur them when it criticized Arizona for rejecting measures without demonstrating that such measures were 'impracticable' or unreasonable.'' *Citizens for a Better Environment* v. *Deukmejian,* 746 F. Supp. 976, 985 (N.D. Cal. 1990). The Court went on to observe that: ''As a practical matter, however, no Court will use its equitable powers to impose remedies that are irrational, albeit 'possible.' Thus as long as time is considered paramount, and the term 'practical' is strictly construed in keeping with the purposes of the Act, the 'as expeditiously as practicable' standard should yield no less results than an 'as soon as possible' standard.'' *Id.*

The Court concluded that ''when properly interpreted, there is no practical difference between the two standards.'' *Id.* EPA agrees with this assessment.

The commenter further complains that EPA's standard does not impose any particular deadline, and that it is too vague and undefined. However, the standard is the very one established in the statute for attainment of the standard, and years of experience in implementation of the statute has provided EPA and the states sufficient familiarity with the standard. Finally, the commenter notes that the states have already submitted ROP plans which the D.C. Circuit has allegedly found deficient for failure to include progress through 2002, thus warranting disapproval. As we stated previously this claim is not relevant to the proposed action, which was for reclassification of the Washington area concurrent with the establishment of a reasonable deadline for submitting SIP revisions. The commenter's contention that the ROP submissions are inadequate for not having ROP for 2002 and 2005 also ignores the fact that reclassification is occurring in 2003, and thus it is impossible for the State to meet the 2002 milestone date. Refer to the discussion in the preceding section entitled ''Severe Area SIP Revision Submittal Schedule'' regarding the impossibility of meeting deadlines that have already passed, and the ROP discussion regarding the Washington area's post-1999 ROP obligation that appears elsewhere in this document.

The severe area ROP plan will also have to provide for the second increment of post-1999 ROP for the period 2002 to 2005 and thus must

achieve a minimum of 18 percent emission reduction from base line emissions by November 15, 2005. Therefore, this delay does not reduce the overall ROP obligation.

With respect to the claim that EPA incorrectly asserted that contingency plans would need to account for any adjustment in the 2002 ROP milestone date, EPA disagrees. As discussed in the preceding paragraphs, EPA reasonably concluded that after 2002 the 2002 ROP milestone date should be adjusted to be ''as expeditiously as practicable,'' and thus contingency measures would properly be keyed to this new date.

The requirements for contingency measures for failure to attain the 1-hour ozone NAAQS by November 15, 2005 or a 2005 ROP milestone failure are not affected by this action.

D. Triggering Implementation of Contingency Measures

Summary of Public Comments Received and EPA's Response

Comment: One commenter urged EPA to specify in the final rulemaking that any adjustment of the 2002 ROP milestone would not trigger or require the implementation of contingency measures in the area.

Response: EPA believes that allowing the first required post-1999 nine percent ROP, due by November 15, 2002, to be demonstrated as expeditiously as practicable after that date does not trigger the need to implement contingency measures prior to that date.

EPA is allowing the District, Maryland and Virginia to demonstrate that the first required post-1999 nine percent ROP, due under the statute by November 15, 2002, as expeditiously as practicable after that date in the event that control measures currently in the SIPs of the District, Maryland and Virginia or already promulgated by EPA, have not already achieved the required nine percent reduction by November 15, 2002. This first post-1999 ROP reduction has to be from base line emissions and account for growth in emissions through November 15, 2002. We have noted that for the Washington area there are emission reductions not relied on or credited in the ROP plan accruing between November 15, 1999, and November 15, 2002, from the January 1, 2000, implementation of phase 2 of the reformulated gasoline program, NO_X reductions beyond RACT, and other on-road measures, such as the national low emission vehicle (NLEV) program, and a variety of off-road national emissions reduction programs. *See* 66 FR at 615, January 3, 2001. These measures have and will continue to provide additional reductions beyond those credited in the area's post-1996 ROP for the November 15, 1999, ROP milestone. These measures meet the ROP creditablity requirements of CAA sections 182(b) and (c) because these measures are already in the approved SIPs or are rules promulgated by the EPA. However, EPA had insufficient information at the time of the November 13, 2002, notice of proposed rulemaking (and currently still has insufficient information) to determine whether or not these measures achieve the required nine percent reduction in base line emissions for the first post-1999 period. One major factor in demonstrating ROP for any milestone year is the release of a revised mobile source emissions factor model, MOBILE6. As discussed elsewhere in this document, as well as in the November 13, 2002, notice of proposed rulemaking (67 FR at 68811) the revised MOBILE6 model must be used for the severe area SIP and the MOBILE6 model must be used to redetermine 1990 base line emissions and prior target levels, as well as the new 2002 and 2005 year target levels and control strategy projections.

In the event that the Washington area can demonstrate that the required nine percent reduction occurred by November 15, 2002, (with the current SIP plus Federal measures), then the contingency requirement will not be triggered. In the event the area cannot demonstrate the required nine percent reduction did occur by November 15, 2002, (with the current SIP plus Federal measures) then EPA has determined that the District, Maryland and Virginia ROP SIP would be able to adjust the milestone date for the first required post-1999 nine percent ROP to a date that is as expeditiously as practicable after November 15, 2002. As explained in prior paragraphs, this is because the statutory 2002 ROP date lapsed before the area was first classified as severe ozone nonattainment. Only a finding that the area failed to achieve the required reductions by that new milestone could trigger the need to implement contingency measures.

E. Impacts on Mobile Source Emissions Budgets and Transportation Planning

Summary of Public Comments Received and EPA's Response

Comment #1: One commenter stated agreement with our assessment that a portion of the Washington area air quality problem is due to transport and agreement that there has been improvement in ozone air quality in the area. For these reasons the commenter asserted that the area should not be subjected to punitive measures such as sanctions, nor subject to lapses or ''freezes'' of the transportation planning processes.

Response #1: This action does not create a ''conformity freeze'' or impose sanctions.[3] Under section 179(a), sanctions can result from an EPA finding that a State failed to submit a required SIP revision (or has submitted one that does not meet the completeness requirements of the CAA and EPA regulations) or other required submission required under the CAA, result from a disapproval of a required submission, or result from a finding that a State is not implementing all or part of its approved SIP.[4] Likewise, under the conformity rule, 40 CFR part 93, a conformity freeze only results when EPA disapproves a ROP or attainment demonstration SIP revision without making a protective finding. *See* 40 CFR 93.120(a)(2). This final rule does none of these things.

Comment #2: One commenter asserted that transportation planning should not be subject to a conformity freeze due to action on the plans subject to the July 2, 2002, Court ruling on EPA's January 3, 2001, final rule on the Washington area SIP.

Response #2: This comment is not germane to this action. EPA did not propose action on any SIP revision in the November 13, 2002, notice of proposed rulemaking. The action EPA takes on the SIP revisions formerly covered by the now vacated January 3, 2001, final rule will be the subject of separate rulemaking action(s). EPA intends to establish in a forthcoming notice of proposed rulemaking in the **Federal Register** a separate public comment period on these SIP revisions.

Comment #3: One commenter stated that the District, Maryland and Virginia had provided MOBILE5 budgets for the Washington area that were found to be adequate. This commenter claimed these budgets were consistent with the attainment plan and were the most recent budgets at the time these budgets were developed. The commenter urged that no conformity freeze should ensue because these budgets are adequate. This commenter urged EPA to allow the area to continue to use any adequate MOBILE5 derived budgets until

[3] In a conformity freeze the only transportation projects that could be found to conform would be those included in the first three years of the currently conforming transportation plan and transportation improvement program (TIP). No new plans, TIPs, or plan/TIP amendments could be found to conform after the effective date of the disapproval.

[4] EPA's completeness criteria that are promulgated pursuant to section 110(k)(1) of the CAA are found in appendix V to 40 CFR part 51.

MOBILE6 based budgets are found to be adequate.

Response #3: This action has no effect on the adequacy status of budgets or the determination of which budgets are in effect. These comments are not germane to this action because EPA did not propose any action on any budgets in the November 13, 2002, notice of proposed rulemaking.

Our discussion of conformity issues in the November 13, 2002, notice of proposed rulemaking was only for the purpose of informing the public of the status of the separate process related to the adequacy status of the budgets in the SIP for which EPA's approval was vacated by the July 2, 2002, court ruling. EPA has taken no final action with respect to adequacy and thus the budgets in the vacated SIPs currently can not be used for conformity. The previously approved ROP budgets in the 15 percent ROP SIPs are currently in effect. (*See* 64 FR 42629, August 5, 1999, 65 FR 44686, July 19, 2000, and 65 FR 59727, October 6, 2000.) *See* the discussion under section XIII of the notice of proposed rulemaking entitled ''What are the Transportation Conformity Implications of Reclassification?'' (67 FR at 68810, November 13, 2002).

F. MOBILE6 Model and the Submittal Schedule

In the November 13, 2002, notice of proposed rulemaking, we discussed the MOBILE6 release to interpret and reiterate application of our guidance affiliated with the January 29, 2002, official release of the MOBILE6 emission factor model to the SIP revisions that the Washington area needed to prepare if the area was reclassified to severe.

Summary of Public Comments Received and EPA's Responses

Comment #1: One commenter claims the MOBILE5 emission factor model lacks the ability to predict real emissions because it uses average trip speed to predict emissions and thus misses the influence of variations in speed on emissions. The commenter further claims that MOBILE6 will have the same imperfection because it merely substitutes average speed on each link for average trip speed. The commenter asserts that MOBILE6 will be replaced in a few years, that this planned replacement shows MOBILE6 is inadequate and that tax dollars should not be spent on using a model that is inadequate for its intended purpose.

Response #1: In the November 13, 2002, notice of proposed rulemaking, we discussed the MOBILE6 release to interpret and reiterate application of our guidance affiliated with the January 29, 2002, official release of the MOBILE6 emission factor model to the severe area SIP revisions that would become due if the Washington area was reclassified to severe. As a consequence, application of our guidance policy relating to the phase-in of MOBILE6 will require additional plan development in the case of the Washington area that would not have occurred otherwise. This increase in scope of the severe area SIP development is one factor in setting the deadline for submission of the severe area SIP.

The Washington area States had submitted a plan to demonstrate that the Washington area would attain the ozone NAAQS by November 15, 2005, once transport-controls implemented in upwind areas have had time to take effect. This plan included, among other things, 2005 motor vehicle emissions budgets, a ROP plan through 1999 and the approved 1990 base year emission inventory. The District, Maryland and Virginia had used the MOBILE5b model to quantify the on-road mobile source emissions for the ROP plan through 1999, the 2005 motor vehicle emissions budgets and the 1990 base year inventory.

If the Washington area had been reclassified to severe nonattainment well before the release of MOBILE6 the existing submittals might have formed part of the severe area SIP by adding the other elements including (but not limited to) ROP plans through 2005, contingency measures and revised major stationary source thresholds and severe area offset ratios. In the absence of an official release of MOBILE6, the States could have continued to use MOBILE5b to develop the missing ROP plans for 2002 and 2005 and to revise the 2005 attainment motor vehicle emissions budgets to reflect any new transportation control measures that might be adopted.

However, MOBILE6, which has been officially released, incorporates numerous changes in emissions that necessitate a revision to the 1990 base year inventory which is, among other things, the planning base line from which the 2002 and 2005 ROP targets are calculated. The changes incorporated into MOBILE6 were not merely limited to coding in the effects of new regulations under the federal motor vehicle control program but also looked at factors and data that result in changed emission rates for 1999 and earlier years. MOBILE6 is a major revision of the MOBILE model. The revision is based on much new data, but also on new understanding of vehicle emission processes. It includes the effects of regulations that have been issued since MOBILE5b was released, and it includes new features designed to make the model more useful. The improvements in the data and calculations have led to improved estimates of highway vehicle emissions. In some cases, the updated MOBILE6 emissions are significantly different from the emissions estimated with MOBILE5.

In the November 13, 2002, notice of proposed rulemaking, EPA intended to state our position that the severe area ROP plan and attainment demonstration need to use MOBILE6 to calculate ROP targets, ROP and attainment motor vehicle emissions budgets using MOBILE6. Because MOBILE6 is the best model currently available and has been officially released, EPA reaffirms that MOBILE6 must be used by Maryland, Virginia and the District of Columbia to quantify mobile source emissions levels and benefits of mobile source emissions control measures and programs when developing the severe area SIP for the Washington area. These uses include (but are not limited to) revision of the1990 base year emissions inventory, development of the target levels for the 2002 and 2005 ROP plans future year emissions projections, and development of motor vehicle emissions budgets.

EPA is currently developing the framework for the model that will eventually replace MOBILE6. While work has begun on the new model, we estimate that it will not be completed until the fall of 2005. In other words, based on EPA's current schedule it is likely that the new model will not be available more than one or two months prior to the area's attainment date of November 15, 2005. Therefore, it is not possible for EPA to allow the area to wait until the new model is available to submit the severe area SIP revisions that are required. For areas reclassified under section 181(b), pursuant to section 182(i) of the CAA EPA can adjust applicable deadlines (other than the attainment date) such as those for submission of a SIP to meet a new classification or achievement of rate-of-progress, but EPA cannot delay the date by which the Washington area must submit the severe area SIP revision submissions past the attainment date.

With regard to the influence of speeds on emissions, EPA concludes that MOBILE6 provides the best estimates of mobile source emissions currently available including consideration of the effects of speed on emissions. Thus EPA believes it is appropriate for the Washington area to use MOBILE6 for current SIP planning. This is for the

reasons discussed in the preceding paragraphs: (1) MOBILE6 is the best model currently available and has been officially released; (2) EPA believes it is unlikely a new model will become available within the time period before the severe area SIPs are due; and (3) because the release date of any successor model cannot be forecast at this time, EPA cannot delay the submittal date indefinitely.

Comment #2: One commenter agreed with EPA that the July 2, 2002, Court ruling vacated approval of the commitment to revise the transportation conformity budgets within one year of the official release of MOBILE6. This commenter urged EPA to set the date by which the area must set transportation conformity budgets using MOBILE6 to coincide with the date by which the severe area plan elements must be submitted.

Response #2: In the November 13, 2002, notice of proposed rulemaking, we discussed the MOBILE6 release to interpret and reiterate application of our guidance affiliated with the January 29, 2002, official release of the MOBILE6 emission factor model to the SIP revisions that would become due if the Washington area was reclassified to severe. Given the time that has now elapsed since the release of the MOBILE6, EPA believes that application of our policy and guidance related to the release of the MOBILE6 model means that MOBILE6 is the only proper model to be used for any motor vehicle emissions budgets submitted to fulfill the severe area requirements.[5]

EPA did not propose action on any SIP revision or on any enforceable commitment in the November 13, 2002, notice of proposed rulemaking for this action. Any action EPA takes on the SIP revisions formerly covered by the now vacated January 3, 2001, final rule will be the subject of separate rulemaking action(s). EPA will establish in a forthcoming notice of proposed rulemaking in the **Federal Register** a separate public comment period on these SIP revisions. EPA anticipates it would not set any different date for submittal of the budgets than the date for submittal of the ROP and attainment demonstration SIP revisions.

G. Need for Mid-Course Review

Summary of Public Comments Received

One commenter agreed with EPA that the July 2, 2002, Court ruling vacated approval of the commitment to perform a mid-course review (MCR). The commenter contended that the schedule for submittal of the severe area SIP might well negate the need for a MCR and asked EPA to specify whether the severe area SIP needs to include a MCR.

EPA's Response

EPA disagrees that the schedule set in this final rule fully negates the need for a commitment to a MCR.

Our 1996 modeling guidance recognizes a need to perform a MCR review as a means for addressing uncertainty in the modeling results.[6] Because of the uncertainty in long term projections, EPA believes a viable attainment demonstration that relies on WOE needs to contain provisions for periodic review of monitoring, emissions, and modeling data to assess the extent to which refinements to emission control measures are needed.

On March 28, 2002, EPA issued further guidance on the performance of the MCR.[7] In this memorandum covered the overall MCR process and timing, including the potential consequences of findings that progress toward attainment is, or is not, being made; guidance for situations where failure to make progress is due to transport; and a special schedule for other (*e.g.*, moderate or serious) ozone nonattainment areas with attainment dates of 2004 or earlier. This memorandum revised some of the earlier policy related to areas in the east significantly affected by transport. Originally we required the Washington area to provide an enforceable commitment to perform the MCR following the 2003 ozone season and to submit the results to EPA by the end of the review year (*i.e.*, December 31, 2003). We chose the end of calendar year 2003 because at the time we had thought that an analysis in 2003 would be most robust since some or all of the regional NO_X emission reductions should be achieved by that date.

In our January 2002, guidance we noted that if a State's implementation plan relies on regional control measures, for a MCR to be useful, a substantial portion of these measures need to have been implemented prior to the most recent ozone season in the nonattainment area for which the MCR is being performed. For example, if NO_X SIP call measures are implemented by the spring of 2004, and those measures are an important part of the strategy for meeting the NAAQS in a particular nonattainment area, the MCR should include data from the Summer of 2004.[8] EPA has already concluded that the Washington area is significantly affected by transport and issued the NO_X SIP call to prohibit specified amounts of emissions of one of the main precursors of ground-level ozone, NO_X, to reduce ozone transport across State boundaries in the eastern half of the United States. *See* 63 FR 57356, October 27, 1998).

While the District, Maryland and Virginia may be able to perform some aspects of the MCR before submission of the severe area SIP, they will not be able to incorporate 2004 air quality data into the analysis. The 2004 air quality data should be the first to reflect control of NO_X throughout the entire eastern half of the United States. EPA believes that the appropriate submission date for the MCR for the Washington area is no later than December 31, 2004, in order to include air quality data that reflects at least one full season of regional NO_X controls. Given that the schedule set in this final rule requires submission of the severe area SIP before December 31, 2004, EPA believes that the Washington area needs to revise its commitment to perform a MCR as part of its severe area SIP. The revised commitment would not have to provide an administrative review of additional measures adopted after reclassification to severe, but would have to address other aspects of a MCR.

H. Guidance on Offsetting Growth in Emissions Due to Growth in Vehicle Miles Traveled (VMT)

Summary of Public Comments Received

One commenter asked for clarification regarding a statement made regarding the enforceable transportation control strategies requirement of section 182(d)(1). The text at issue in the proposal was found in item number four in section XII of the proposed rule (67 FR at 68810) which was entitled ''What would a Reclassification Mean for the Washington Area?'', November 13, 2002). The commenter noted a discrepancy between the description in the notice of proposed rulemaking and the language found in the statute. The commenter stated that section 182(d)(1) of the CAA requires a State to submit a

[5] The applicable guidance and policy can be found in the January 18, 2002, joint memorandum from John S. Seitz and Margo Tsirigotis Oge entitled ''Policy Guidance for the Use of MOBILE6 in SIP Development and Transportation Conformity.''

[6] *See* ''Guidance on Use of Modeled Results to Demonstrate Attainment of the Ozone NAAQS'', EPA–454/B–95–007, June 1996.

[7] *See* ''Mid-Course Review Guidance for the 1-Hour Ozone Nonattainment Areas that Rely on Weight-of-Evidence for Attainment Demonstration,'' from Lydia N. Wegman, Director, Air Quality Strategies & Standards Division, OAQPS and J. David Mobley, Acting Director, Emissions, Monitoring and Analysis Division, OAQPS, dated March 28, 2002, and *see* ''Recommended Approach For Performing Mid-course Review of SIP's To Meet The 1-hour NAAQS For Ozone,'' January 2002.

[8] *Ibid.*

revision ''that identifies and adopts specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such area and to attain reduction in motor vehicle emissions as necessary, in combination with other emission reduction requirements of this subpart, to comply with the requirements of subsection (b)(2)(B) and (c)(2)(B) (pertaining to periodic emissions reduction requirements). The State shall consider measures specified in section 108(f), and choose from among and implement such measures as necessary to demonstrate attainment.'' In contrast the notice of proposed rulemaking stated ''[e]nforceable transportation control strategies and measures to offset projected growth in vehicle miles traveled or number of vehicle trips as necessary to demonstrate attainment and to achieve periodic emissions reduction requirements''.

The commenter asserted that if EPA was changing the requirement for the Washington area from a requirement for measures to offset growth in vehicle emissions due to VMT growth or number of vehicle trips as necessary to attain or achieve ROP to one requiring measures to offset VMT growth or number of vehicle trips then EPA needs to conduct formal notice and comment rulemaking.

EPA's Response

EPA intent in section XII entitled ''What would a Reclassification Mean for the Washington Area'' of the notice of proposed rulemaking was not to change any requirement or any change current guidance or policy. In section XII of the notice of proposed rulemaking we merely outlined some of the major planning elements that the Washington area would have to include in a severe area SIP. EPA agrees that the summary description provided in the notice of proposed rulemaking would have better reflected the statutory requirement if it had said ''enforceable transportation control strategies and measures to offset any growth in emissions due to projected growth in vehicle miles traveled or number of vehicle trips as necessary to demonstrate attainment and to achieve periodic emissions reduction requirements.''

I. 2002 Air Quality Data and Air Quality Improvement Since 1990

Summary of Public Comments Received

One commenter does not agree with EPA's statement in the notice of proposed rulemaking that the air quality in the Washington area has improved significantly since 1990. The commenter claims the notice failed to consider air quality data for the 2002 ozone season and that the 2002 ozone season was the worst in a decade because their were nine days during which at least one monitor exceeded the 1-hour ozone NAAQS.

EPA's Response

Some of the air quality data trends presented in the notice of proposed rulemaking were for informational purposes only and do not form the basis for the action we announce in this document. The data relevant for purposes of making the statutory determination of whether the area attained by its deadline is that which shows the area did not attain by November 15, 1999.

As explained elsewhere in this document, section 181(b)(2)(A) of the Clean Air Act requires that when EPA determines that an area has not attained the standard by its statutorily required date the area shall be reclassified by operation of law to the higher of—

(1) The next higher classification for the area, or

(2) The classification applicable to the area's design value as determined at the time EPA publishes its notice that the area failed to attain.

Therefore, even if a serious area's design value at the time of reclassification is lower than the design value for serious nonattainment, that serious area cannot be reclassified to a lower classification because the minimum reclassification resulting from a failure to attain is severe. Likewise, the maximum reclassification is severe because even if an area's design value is beyond the extreme threshold section 181(b)(2) prohibits an area failing to attain from being reclassified to extreme nonattainment.

Therefore, unlike a marginal or moderate nonattainment area where the design value at the time of the reclassification could have a bearing on the final classification resulting from a failure to attain, a serious area can only be reclassified under section 181(b)(2) to severe nonattainment upon a finding of failure to attain because the only operative provision is that which requires reclassification to the next higher classification.

The design value data in the notice of proposed rulemaking was presented mainly as an indicator that had the area been classified for the first time, the area would have been classified as marginal.

The relevant air quality data for EPA's final determination of a failure to attain is that which shows the area contained at least one monitor with an average annual number of expected exceedances for the 1997 through 1999, inclusive, period.

With respect to the 2002 air quality data , we did not present it in the notice of proposed rulemaking for the simple reason that insufficient final data was available for us to make a proper comparison with prior years data at the time the notice of proposed rulemaking was drafted.

Even taking into account the 2002 data, the Washington area's design value corresponds to that of a marginal area. The Washington area's air quality has by this measure improved from the time it was classified as a serous area based upon its design value.

J. Adequacy of Current SIP Submittals

Summary of Public Comments Received

One commenter does not agree that the Washington area states had ever submitted a modeled demonstration of attainment for the area.

EPA's Response

This comment is not germane to this action. EPA did not propose action on any SIP revision in the November 13, 2002, notice of proposed rulemaking. What action EPA takes on the SIP revisions formerly covered by the now vacated January 3, 2001, final rule will be the subject of separate rulemaking action(s). EPA will establish in a forthcoming notice of proposed rulemaking in the **Federal Register** a separate public comment period on these SIP revisions.

IV. What Is the Impact of Reclassification on Title V Operating Permit Programs?

In the November 13, 2002, notice of proposed rulemaking, EPA noted that additional sources would become subject to the Title V major stationary source operating permit program as a collateral consequence of a reclassification of the Washington area to severe. The affected sources are those with a potential to emit of more than 25 tons per year of either VOC or NO_X or both VOC and NO_X. Any newly major stationary sources must submit a timely Title V permit application. ''A timely application for a source applying for a part 70 permit for the first time is one that is submitted within 12 months after the source becomes subject to the permit program or on or before such earlier date as the permitting authority may establish.'' *See* 40 CFR 70.5(a)(1) and *see* 40 CFR 71.5(a)(1). On the effective date of this action that can be found in the **DATES** section of this final rule, the

12 month (or earlier date set by the applicable permitting authority) time period to submit a timely application will commence in accordance with the state Title V program regulations applicable to that source.[9]

V. Final Action

For the reasons set forth in the notice of proposed rulemaking and in this final rulemaking notice, EPA has determined that the Washington ozone nonattainment area failed to attain the 1-hour ozone NAAQS by November 15, 1999, as required by section 181(a) of the CAA, and the Washington ozone nonattainment area is reclassified by operation of law to severe ozone nonattainment pursuant to section 181(b)(2) of the CAA.

A. What Is the New Attainment Date for the Washington Area?

Under section 181(a)(1) of the CAA, the new attainment deadline for the Washington area as a serious ozone nonattainment areas reclassified to severe under section 181(b)(2) is to attain the 1-hour ozone NAAQS as expeditiously as practicable but no later than November 15, 2005, which is the date applicable to the new severe nonattainment classification.

B. When Must District of Columbia, Maryland and Virginia Submit SIP Revisions Fulfilling the Requirements for Severe Ozone Attainment Areas?

Under section 181(a)(1) of the Act, the attainment deadline for serious ozone nonattainment areas reclassified to severe under section 181(b)(2) is as expeditiously as practicable but no later than November 15, 2005. Under section 182(i), such areas are required to submit SIP revisions addressing the severe area requirements for the 1-hour ozone NAAQS. Under section 182(d), severe area plans are required to meet all the requirements for serious area plans plus the requirements for severe areas, including, but not limited to: (1) A 25 ton per year major stationary source threshold; (2) additional reasonably available control technology (RACT) rules for sources subject to the new lower major applicability cutoff; (3) a new source review (NSR) offset requirement of at least 1.3 to 1; (4) a post-1999 rate-of-progress plan with on-road mobile source emission budgets in emission reductions of ozone precursors of at least 3 percent per year from November 15, 1999 until the attainment date; and (5) a fee requirement for major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X) should the area fail to attain by 2005.[10] We have issued a ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'' that sets forth our preliminary views on these section 182 requirements and how we will act on SIPs submitted under Title I. *See* 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992).

The District's, Maryland's and Virginia's severe ozone SIP for the Washington area must also contain adopted regulations, and/or enforceable commitments to adopt and implement control measures in regulatory form by specified dates, sufficient to make the required rate-of-progress and to attain the 1-hour ozone NAAQS as expeditiously as practicable but no later than November 15, 2005. Section 182(i) further provides that we may adjust the CAA deadlines for submitting these severe area SIP requirements. In addition to establishing a new attainment date, EPA must also address the schedule by which the District, Maryland and Virginia are required to submit SIP revisions meeting the CAA's pollution control requirements for severe areas.

For the reasons set forth in the notice of proposed rulemaking and this final rulemaking notice and pursuant to section 182(i) of the CAA, EPA is requiring the District of Columbia, Maryland and Virginia to submit SIP revisions addressing the CAA's pollution control requirements for severe ozone nonattainment areas by March 1, 2004.

C. What Will Be the Rate-of-Progress (ROP) and Contingency Measure Schedules?

For the reasons set forth in the notice of proposed rulemaking and this final rulemaking notice and pursuant to section 182(i) of the CAA, EPA is allowing the District, Maryland and Virginia to demonstrate the first required post-1999 nine percent ROP, due under the CAA by November 15, 2002, as expeditiously as practicable after that date (but in any case no later than November 15, 2005) in the event that control measures currently in the SIPs of the District, Maryland and Virginia or already promulgated by EPA do not achieve the required nine percent reduction by November 15, 2002.

The severe area SIP will have to provide for a total of a 18 percent reduction from base line emissions between November 15, 1999, through November 15, 2005. Because the 2002 ROP deadline is now past, the first 9 percent reduction requirement for the period 1999 to 2002 will have to be achieved as expeditiously as practicable after November 15, 2002. The second 9 percent reduction in base line emissions must be achieved by November 15, 2005, to address the 2002 through 2005 ROP requirement. Additionally, the area must submit adequate on-road mobile source emission budgets consistent with the 2002 and 2005 ROP plans.

Because EPA is allowing the District, Maryland and Virginia to demonstrate the first required post-1999 nine percent ROP, due under the CAA by November 15, 2002, as expeditiously as practicable after that date (but in any case no later than November 15, 2005), EPA is also allowing the District, Maryland and Virginia to adopt contingency measures keyed to this new date.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA is required to determine whether regulatory actions are significant and therefore should be subject to Office of Management and Budget (OMB) review, economic analysis, and the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f), including, under paragraph (1), that the rule may ''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.''

The Agency has determined that the finding of nonattainment would result in none of the effects identified in section 3(f) of the Executive Order. Under section 181(b)(2) of the CAA, determinations of nonattainment are based upon air quality considerations and the resulting reclassifications must occur by operation of law. They do not, in and of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those

[9] Or, in the absence of an applicable state permit program covering the affected source, *see* 40 CFR 71.5(a)(1).

[10] Section 182(d)(3) sets a deadline of December 31, 2000, to submit the plan revision requiring fees for major sources should the area fail to attain. This date can be adjusted pursuant to CAA section 182(i). We proposed to adjust this date to coincide with the submittal deadline for the rest of the severe area plan requirements.

requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, determinations of nonattainment and reclassification cannot be said to impose a materially adverse impact on state, local, or tribal governments or communities.

B. National Technology Transfer and Advancement Act

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*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final action to reclassify the Washington, DC area as a severe ozone nonattainment area and to adjust applicable deadlines does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

C. Paperwork Reduction Act

This final action to reclassify the Washington, DC area as a severe ozone nonattainment area and to adjust applicable deadlines does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

D. Regulatory Flexibility Act

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

Determinations of nonattainment and the resulting reclassification of nonattainment areas by operation of law under section 181(b)(2) of the CAA do not in and of themselves create any new requirements. Instead, this rulemaking only makes a factual determination, and does not directly regulate any entities. *See* 62 FR 60001, 60007–8, and 60010 (November 6, 1997) for additional analysis of the RFA implications of attainment determinations. Therefore, pursuant to 5 U.S.C. 605(b), I certify that this final action does not have a significant impact on a substantial number of small entities within the meaning of those terms for RFA purposes.

E. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA believes, as discussed previously in this document, that the finding of nonattainment is a factual determination based upon air quality considerations and that the resulting reclassification of the area must occur by operation of law. Thus, EPA believes that the proposed finding does not constitute a Federal mandate, as defined in section 101 of the UMRA, because it does not impose an enforceable duty on any entity.

F. 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. This final action is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866.

G. Executive Order 13132, Federalism

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by state and local officials in the development of regulatory policies that have Federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by state and local governments, or EPA consults with state and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has Federalism implications and that preempts state law unless the Agency consults with state and local officials early in the process of developing the proposed regulation. This determination of nonattainment and the resulting reclassification of a nonattainment area by operation of law 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), because this action does not, in and of itself, impose any new requirements on any sectors of the economy, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. Thus, the requirements of section 6 of the Executive Order do not apply to these actions.

H. Executive Order 13175, Coordination With Indian Tribal Governments

This final rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

I. Executive Order 13211, Actions that Significantly Affect Energy Supply, Distribution, or Use

Under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), EPA must prepare for those matters identified as significant energy actions. A ''significant energy action'' is 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 that is a significant regulatory action under Executive Order 12866 and, and is likely to have a significant adverse effect on the supply, distribution, or use of energy. Under Executive Order 12866, this action is not a ''significant regulatory action.'' For this reason, the proposed finding of nonattainment and reclassification is also not subject to Executive Order 13211.

J. 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**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

K. 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 March 25, 2003. 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 to reclassify the Washington, DC area as a severe ozone attainment area and to adjust applicable deadlines may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2)).

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: January 15, 2003.

Donald S. Welsh,

Regional Administrator, Region III.

Accordingly, 40 CFR part 81 is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

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

2. Section 81.309 is amended by revising the ozone table entry for the Washington area to read as follows:

§ 81.309 District of Columbia.

* * * * *

DISTRICT OF COLUMBIA—OZONE

[1-Hour Standard]

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
Washington Area: Washington Entire Area	.....	Nonattainment	3/25/03	Severe

[1] This date is November 15, 1990, unless otherwise noted.

* * * * *

3. Section 81.321 is amended by revising the ozone table entry for the Washington, DC area to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND—OZONE

[1-Hour Standard]

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
* * * * * * *				
Washington, DC Area:				
Calvert County	.....	Nonattainment	3/25/03	Severe
Charles County	.....	Nonattainment	3/25/03	Severe
Frederick County	.....	Nonattainment	3/25/03	Severe
Montgomery County	.....	Nonattainment	3/25/03	Severe
Prince George's County	.....	Nonattainment	3/25/03	Severe
* * * * * * *				

[1] This date is October 18, 2000, unless otherwise noted.

* * * * *

4. Section 81.347 is amended by revising the ozone table entry for the Washington area to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA—OZONE

[1-Hour Standard]

Designated area	Designation		Classification	
	Date[1]	Type	Date[1]	Type
* * *	*	*	*	*
Washington, DC Area:				
Alexandria		Nonattainment	3/25/03	Severe
Arlington County		Nonattainment	3/25/03	Severe
Fairfax		Nonattainment	3/25/03	Severe
Fairfax County		Nonattainment	3/25/03	Severe
Falls Church		Nonattainment	3/25/03	Severe
Loudoun County		Nonattainment	3/25/03	Severe
Manassas		Nonattainment	3/25/03	Severe
Manassas Park		Nonattainment	3/25/03	Severe
Prince William County		Nonattainment	3/25/03	Severe
Stafford County		Nonattainment	3/25/03	Severe
* * *	*	*	*	*

[1] This date is October 18, 2000, unless otherwise noted.

* * * * *

[FR Doc. 03–1515 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0086; FRL–7187–3]

Oxadiazon; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document revokes all tolerances for residues of the herbicide oxadiazon. The regulatory actions in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. The regulatory actions in this document pertain to the revocation of 16 tolerances which were previously reassessed and counted.

DATES: This regulation is effective April 24, 2003. Objections and requests for hearings, identified by docket identification (ID) number OPP–2002–0086, must be received on or before March 25, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Registration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8037; e-mail address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer.

Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2002–0086. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under 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.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background

A. What Action is the Agency Taking?

In the **Federal Register** of August 1, 2001 (66 FR 39705) (FRL–6786–4), EPA issued a proposed rule to revoke all tolerances for oxadiazon and tetradifon. Also, the August 1, 2001 proposal provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under FFDCA standards.

This final rule revokes all FFDCA tolerances for residues of the herbicide oxadiazon because this pesticide active ingredient is not registered under FIFRA for food uses. The tolerances revoked by this final rule are no longer necessary to cover residues of the relevant pesticides in or on domestically treated commodities or commodities treated outside but imported into the United States. Oxadiazon is no longer used on the commodities associated with those tolerances within the United States. No one commented that there was a need for EPA to retain the tolerances to cover oxadiazon residues in or on imported foods. However, EPA did receive a comment regarding the need for the Agency to retain tetradifon tolerances.

EPA has historically expressed a concern that retention of tolerances that are not necessary to cover residues in or on legally treated foods has the potential to encourage misuse of pesticides within the United States. Thus, it is EPA's policy to issue a final rule revoking those tolerances for residues of pesticide chemicals for which there are no active registrations under FIFRA, unless any person commenting on the proposal demonstrates a need for the tolerance to cover residues in or on imported commodities or domestic commodities legally treated.

Generally, EPA will proceed with the revocation of these tolerances on the grounds discussed in Unit II.A. if one of these conditions applies, as follows:

1. Prior to EPA's issuance of a section 408(f) order requesting additional data or issuance of a section 408(d) or (e) order revoking the tolerances on other grounds, commenters retract the comment identifying a need for the tolerance to be retained.

2. EPA independently verifies that the tolerance is no longer needed.

3. The tolerance is not supported by data that demonstrate that the tolerance meets the requirements under FQPA.

Today's final rule does not revoke those tolerances for which EPA received comments stating a need for the tolerance to be retained. In response to the proposal published in the **Federal Register** of August 1, 2001 (66 FR 39705), EPA did receive comment regarding the need to retain tetradifon tolerances, as follows:

1. *Tetradifon*. EPA received a comment from Uniroyal Chemical, who requested the retention of tetradifon tolerances. Uniroyal noted that it had submitted certain studies to EPA in 1998 and 1996 and awaits determination of their acceptability by the Agency, and until those determinations are made cannot decide whether to support the tetradifon tolerances. Uniroyal added it would support two tolerances to allow importation of those tetradifon-treated food commodities, but did not name them.

In follow-up communication, Uniroyal expressed interest in maintaining tolerances for apples, citrus, and some vegetables, but did not commit to support any tetradifon tolerances. Also, in follow-up communication, Uniroyal acknowledged that it has not pursued correspondence with EPA since 1998 regarding disposition of the submitted studies nor submitted a registration petition.

Agency Response. EPA is still evaluating the issues described in the comment. Therefore, EPA is not taking final action on the tetradifon tolerances in 40 CFR 180.174 at this time, but may do so after evaluation of these issues.

No comments were received by the Agency concerning oxadiazon.

2. *Oxadiazon*. There have been no active registrations for oxadiazon concerning food uses since 1991. In a confirmatory letter to EPA, dated January 24, 2001, the registrant maintained its previous position that it will not support the 16 oxadiazon tolerances; although, it is supporting the continued (noncrop) use of oxadiazon for turf and ornamentals. Therefore, EPA is revoking all the tolerances in 40 CFR 180.346 for the combined residues of the herbicide oxadiazon and its metabolites in or on milk; cattle, fat; cattle, meat; cattle, meat byproducts; goats, fat; goats, meat; goats, meat byproducts; hogs, fat; hogs, meat; hogs, meat byproducts; horses, fat; horses, meat; horses, meat byproducts; sheep, fat; sheep, meat; and sheep, meat byproducts. The Agency is removing 40 CFR 180.346 in its entirety.

In addition, because EPA determined on April 21, 2002 that there is no reasonable expectation of finite residues of oxadiazon and its metabolites in or on meat, milk, poultry, and egg commodities, the 16 associated tolerances for livestock commodities were considered by the Agency to no longer be needed under 40 CFR 180.6(a)(3). Therefore, on June 3, 2002, the Agency considered the FQPA safety finding to be met and counted the 16 oxadiazon livestock tolerances as reassessed. Copies of these Agency memoranda will be placed in the public docket.

B. What is the Agency's Authority for Taking this Action?

It is EPA's general practice to propose revocation of tolerances for residues of pesticide active ingredients on crop uses for which FIFRA registrations no longer exist. EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Nonetheless, EPA will establish and maintain tolerances even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as ''import tolerances,'' are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

C. When Do These Actions Become Effective?

These actions become effective 90 days following publication of this final rule in the **Federal Register**. EPA has delayed the effectiveness of these revocations for 90 days following publication of this final rule to ensure that all affected parties receive notice of EPA's actions. Consequently, the effective date is April 24, 2003. For this final rule, tolerances that were revoked because registered uses did not exist concerned uses which have been canceled for more than a year. Therefore, commodities containing

these pesticide residues should have cleared the channels of trade.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to this final rule, and that are in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by the FQPA. Under this section, any residue of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of FDA that: (1) The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and (2) the residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from a tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

D. What is the Contribution to Tolerance Reassessment?

By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. As of January 3, 2003, EPA has reassessed over 6,490 tolerances. In this final rule, EPA is revoking 16 tolerances. These tolerances were previously reassessed and counted as described in Unit II.A.

III. Are There Any International Trade Issues Raised by this Final Action?

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual REDs. The U.S. EPA has developed guidance concerning submissions for import tolerance support (65 FR 35069, June 1, 2000) (FRL–6559–3). This guidance will be made available to interested persons. Electronic copies are available on the internet at http://www.epa.gov/. On the Home Page select ''Laws and Regulations,'' then select ''Regulations and Proposed Rules '' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

IV. 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.

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 ID number OPP–2002–0086 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 March 25, 2003.

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 issue(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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IV.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.1. Mail your copies, identified by docket ID number OPP–2002–0086, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

V. Statutory and Executive Order Reviews

This final rule revokes tolerances established under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted this type of action (i.e., a tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other 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).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this rule, I certify that this action will not have a significant economic impact on a substantial number of small entities. Specifically, as per the 1997 notice, EPA has reviewed its available data on imports and foreign pesticide usage and concludes that there is a reasonable international supply of food not treated with oxadiazon. Furthermore, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. 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 section 408(n)(4) of the FFDCA. 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.

VI. 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: January 3, 2003.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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.

§ 180.346 [Removed]

2. Section 180.346 is removed.

[FR Doc. 03–1518 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7442–8]

Ohio: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is granting Ohio final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA published a proposed rule on October 21, 2002, and provided an opportunity for public comment. The public comment period ended on December 5, 2002. EPA received no comments. No further opportunity for public comment will be provided. EPA has determined that Ohio's revisions satisfy all requirements necessary for final authorization and is authorizing Ohio's revised program through this final action.

EFFECTIVE DATE: Final authorization for revisions to Ohio's hazardous waste management program will become effective on January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Feigler, Ohio Regulatory Specialist, U.S. Environmental Protection Agency, Waste, Pesticides and Toxics Division (DM–7J), 77 W. Jackson Blvd., Chicago, Illinois 60604, phone number: (312) 886–4179.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States that have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program which is equivalent to, consistent with, and no less stringent than the federal program. As the federal program changes, states must revise their programs and ask EPA to authorize the revisions. Revisions to state programs may be necessary when federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, states must revise their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Were the Comments and Responses to EPA's Proposal?

On October 21, 2002, EPA published a proposed rule (see 67 FR 64594). In the rule, EPA proposed granting authorization of revisions to Ohio's hazardous waste program and provided an opportunity for public comment. EPA received no comments on the proposal.

C. What Decisions Have We Made in This Rule?

EPA has determined that Ohio's revisions to its authorized program meet all the statutory and regulatory requirements established by RCRA. Therefore, EPA grants Ohio final authorization to operate its hazardous waste program with the revisions described in the authorization application. Ohio now has responsibility for permitting treatment, storage, and disposal facilities (TSDFs) within its borders (except in Indian country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New federal requirements and prohibitions imposed by federal regulations promulgated by EPA under the authority of HSWA take effect in authorized states before the states are authorized for the requirements. Thus, EPA implements those requirements and prohibitions in Ohio, including issuing permits, until Ohio is granted authorization to do so.

D. What Revisions Are We Authorizing With Today's Action?

On June 25, 2002, Ohio submitted a complete program revision application, seeking authorization of its revisions in accordance with 40 CFR 271.21. EPA now makes a final decision that Ohio's hazardous waste management program, as revised, satisfies all requirements under RCRA necessary to qualify for final authorization. Therefore, EPA grants Ohio final authorization for the program revisions described in the October 21, 2002, proposed rule (67 FR 64594). For further details, see the October 21, 2002 proposed rule.

E. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Ohio that is subject to RCRA will now have to comply with the authorized state requirements in lieu of the corresponding federal requirements in order to comply with RCRA. Such facilities must also comply with any applicable federally-issued requirements, such as, for example, HSWA regulations issued by EPA for which Ohio has not received authorization, and RCRA requirements that are not supplanted by authorized state-issued requirements. Ohio will issue permits for all provisions for which it is authorized and will administer the permits that it issues. Ohio continues to have enforcement responsibility under its state hazardous waste management program for violations of that program, but EPA retains authority under RCRA sections 3007, 3008, 3013 and 7003 (42 U.S.C. 6927, 6928, 6934 and 6973) which includes, among others, the authority to:

- Conduct inspections and require monitoring, tests, analyses or reports;
- Enforce RCRA requirements and suspend or revoke permits; and
- Take enforcement action regardless of whether Ohio has taken its own actions.

Today's action to approve these revisions does not impose additional requirements on the regulated community because the regulations included in the program revisions affected by this authorization decision are already effective under state law and are not changed by today's action.

F. Who Handles Permits After the Authorization Takes Effect?

Ohio will issue permits for all provisions for which it is authorized and will administer the permits that it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits that EPA issued prior to the effective date of this authorization, until they expire or are terminated. EPA will not issue any more new permits or new portions of permits for the provisions for which Ohio is authorized after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Ohio is not yet authorized.

G. What Has Ohio Previously Been Authorized for?

Ohio initially received final authorization effective June 30, 1989 (54 FR 27170–27174, June 28, 1989) to implement the RCRA hazardous waste management program. We granted authorization for changes to Ohio's program effective June 7, 1991 (56 FR 14203, April 8, 1991), as corrected June 7, 1991 (56 FR 28808, June 19, 1991); effective September 25, 1995 (60 FR 51244, July 27, 1995); and effective December 23, 1996 (61 FR 54950, October 23, 1996).

H. What Is the Effect of Authorizing Ohio for These Revisions on Indian Country (18 U.S.C. 1151) in Ohio?

Ohio is not authorized to carry out its hazardous waste program in ''Indian

country,'' as defined in 18 U.S.C. 1151. Indian country includes:

1. All lands within the exterior boundaries of Indian reservations within or abutting the State of Ohio;
2. Any land held in trust by the U.S. for an Indian tribe; and
3. Any other land, whether on or off an Indian reservation that qualifies as Indian country. Therefore, this action has no effect on Indian country. EPA retains the authority to implement and administer the RCRA program in Indian country. However, at this time, there is no Indian country within the State of Ohio.

I. What Is Codification and Is EPA Codifying Ohio's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing a state's statutes and regulations that comprise the state's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized state rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart P, for authorization of Ohio's program revisions until a later date.

J. Administrative Requirements

The Office of Management and Budget has exempted RCRA authorization from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. Furthermore, this action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by state law. This authorization will effectively suspend the applicability of certain federal regulations in favor of Ohio's program, thereby eliminating duplicate requirements in the state. Authorization will not impose any new burdens on small entities. Accordingly, I certify that this action 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 action authorizes 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 (Pub. L. 104–4). This action does not have tribal implications within the meaning of Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes state requirements as part of the state RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action does not include environmental justice-related issues that require consideration under Executive Order 12898 (59 FR 7929, February 16, 1994).

Under RCRA section 3006(b), EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) 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 action 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 document 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 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).

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: January 9, 2003.

Bharat Mathur,

Deputy Regional Administrator, Region 5.

[FR Doc. 03–1626 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 312

[FRL–7442–4]

RIN 2050–AF05

Clarification to Interim Standards and Practices for All Appropriate Inquiry Under CERCLA and Notice of Future Rulemaking Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to clarify a provision included in recent amendments to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Specifically, today's direct final rule addresses the interim standard set by Congress in the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Law'') for conducting ''all appropriate inquiry'' to establish that a landowner had no reason to know of contamination at a property under CERCLA liability provisions prior to purchasing the property. Today's action clarifies that, in the case of property purchased on or after May 31, 1997, the requirements for conducting ''all appropriate inquiry,'' including the

conduct of such activities to establish an innocent landowner defense under CERCLA, also will be satisfied through the use of ASTM Standard E1527–2000, entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.'' In addition, recipients of brownfields site assessment grants will be in compliance with the all appropriate inquiry requirements if they comply with the ASTM Standard E1527–2000.

DATES: This rule is effective on March 25, 2003, without further notice, unless EPA receives adverse comment by February 24, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments on today's direct final rule may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions provided in paragraph B of the **SUPPLEMENTARY INFORMATION** section below. Please reference Docket number SFUND–2002–0007 when submitting your comments.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/CERCLA Call Center at 800–424–9346 or TDD 800–553–7672 (hearing impaired). In the Washington, DC metropolitan area, call 703–412–9810 or TDD 703–412–3323.

For more detailed information on specific aspects of this rule, contact Patricia Overmeyer, Office of Brownfields Clean up and Redevelopment (5105T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0002, 202–566–2774. *overmeyer.patricia@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

A. How Can I Get Copies of the Background Materials Supporting Today's Direct Final Rule or Other Related Information?

1. EPA has established an official public docket for this direct final rule under Docket ID No. SFUND–2002–0007. The official public docket consists of the documents specifically referenced in this rule and other information related to this direct final rule. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center located at 1301 Constitution Ave. NW, Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (202) 566–0276. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI, and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified above.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff. For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA will not consider late comments in formulating a final decision.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the party submitting the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. To access EPA's electronic public

docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. SFUND–2002–0007. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

2. E-mail. Comments may be sent by electronic mail (e-mail) to *Superfund.Docket@epamail.epa.gov.* Make sure this electronic copy is in an ASCII format that does not use special characters or encryption. Cite the docket Number SFUND–2002–0007 in your electronic file. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

3. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified above. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

4. By Mail. Send two (2) copies of your comments to: EPA Docket Center, U.S. Environmental Protection Agency Headquarters, Mail Code 5305T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. SFUND–2002–0007.

5. By Hand Delivery or Courier. Deliver your comments to: EPA Docket Center, EPA West Building, Room B–102, 1301 Constitution Ave., NW., Washington, DC, 20007. Attention Docket ID No. SFUND–2002–0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified above.

Regulated Entities

Entities potentially regulated by this action include public and private parties who, as bona fide prospective purchasers, contiguous property owners, or innocent landowners, purchase property and intend to claim a limitation on CERCLA liability in conjunction with the property purchase. In addition, any entity conducting a site characterization or assessment with a brownfields grant awarded under CERCLA section104(k)(2)(B)(ii) will be affected by today's action. This includes state, local and Tribal governments that receive brownfields site assessment grants. A summary of the potentially affected industry sectors (by NAICS codes) is displayed in the table below.

Industry category	NAICS code
Real Estate	531
Insurance	52412
Banking/Real Estate Credit	52292
Environmental Consulting Services	54162
State, Local and Tribal Government	N/A

The list of potentially affected entities in the above table may not be exhaustive. Our aim is to provide a guide for readers regarding those entities that EPA is aware potentially could be affected by this action. However, this action may affect other entities not listed in the table. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

Preamble

I. Statutory Authority
II. Background
III. Today's Action
IV. Future Rulemaking Setting Standards for ''All Appropriate Inquiry'
V. Statutory and Executive Order Reviews

I. Statutory Authority

This direct final rule clarifies provisions included in section 223 of the Small Business Liability Relief and Brownfields Revitalization Act which amends section 101(35)(B) of CERCLA (42 U.S.C. 9601(35)) and clarifies interim standards for the conduct of ''all appropriate inquiry'' for obtaining CERCLA liability relief and for conducting site characterizations and assessments with the use of brownfields grant monies.

II. Background

On January 11, 2002, President Bush signed the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Law''). In general, the Act amends CERCLA and provides funds to assess and clean up brownfields sites; clarifies CERCLA liability provisions related to innocent purchasers of contaminated properties; and provides funding to enhance State and Tribal clean up programs. In part, subtitle B of Title II of the Act revises some of the provisions of CERCLA section 101(35) and provides some Superfund liability limitations for bona fide prospective purchasers and contiguous property owners, in addition to clarifying the requirements necessary to establish the innocent landowner defense under CERCLA. Among the requirements added to CERCLA is the requirement that such parties undertake ''all appropriate inquiry'' into prior ownership and use of certain property.

The Act requires EPA to develop regulations within two years which will establish standards and practices for how to conduct all appropriate inquiry. In addition, in the Brownfields Law, Congress established, as the Federal interim standard for conducting all appropriate inquiry, the procedures of the American Society for Testing and Materials (ASTM) including Standard E1527–97 (entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process''). This interim standard applies to properties purchased on or after May 31, 1997 until EPA promulgates Federal regulations establishing standards and practices for conducting all appropriate inquiry.

Today's direct final rule clarifies that persons may use the current ASTM standard, E1527–2000 for conducting all appropriate inquiry and establishing the innocent landowner defense under CERCLA section 101(35)(B) for properties purchased on or after May 31, 1997, while continuing also to recognize use of ASTM's previous standard, E1527–97.

Following enactment of the Brownfields Law, EPA received inquiries from interested parties expressing concerns that the ASTM standard for all appropriate inquiry that was cited in the Act (*i.e.*, ASTM's 1997 standard) has been updated and consequently is no longer available from ASTM. The ASTM standard cited in the Brownfields Law has been updated and replaced with ASTM's revised standard, ''Standard E1527–2000.'' The revised standard has the same name as the previous standard. The revised standard is not significantly different from the previous standard. Revisions to the 1997 standard that are incorporated into the E1527–2000 updated standard include provisions for potential expansion of an assessment, guidance for better identification of the purpose of the assessment, a provision for inquiring about historical remediation, a provision for facilitating reconstruction of the assessment by a different assessor, and amended guidance for selecting an environmental professional. A summary of the revisions made to the 1997 ASTM standard and included in the 1527–2000 standard is provided in the document ''Overview of Additions and Modifications to ASTM 1527–2000

Standard from the 1997 ASTM Standard.'' A copy of this document, as well as an annotated copy of the 1997 ASTM standard identifying the specific modifications incorporated into the ASTM 2000 standard, is included in the regulatory docket for today's rule.

EPA believes that it is consistent with Congressional intent to require the use of the most current standards available until EPA has promulgated its standard and not to require the use of standards that have been superseded or that generally are not available. In addition, Congress did not intend to place an undue burden on interested parties seeking to obtain and implement the standard. Given that the version of the ASTM standard cited in the Brownfields Law is no longer available, such an undue burden may occur, if EPA does not undertake today's action. In particular, recipients of grant monies awarded under the new Brownfields Law may experience an undue burden, if required to comply with the ASTM standard that no longer is available or recognized as the current industry standard. Therefore, with today's action, EPA is clarifying that for the purposes of CERCLA section 101 (35)(B), until the Agency promulgates regulations implementing standards for all appropriate inquiry, parties may use either the procedures provided in ASTM E1527–2000, entitled ''Standard Practice for Environmental Site Assessment: Phase I Environmental Site Assessment Process,'' or the standard ASTM E1527–97. EPA has determined that it is reasonable to promulgate this clarification as a direct final rule that is effective immediately, rather than delay promulgation of the clarification until after receipt and consideration of public comments, to avoid any further confusion with regard to the acceptable standard for conducting all appropriate inquiry and to ensure that new grant recipients are not placed under any undue burden.

III. Today's Action

EPA is publishing this direct final rule because the Agency wants to reduce any undue burden placed upon grant recipients. In addition, the Agency views this as a noncontroversial action and anticipates no adverse comment. We believe that today's action is reasonable and can be promulgated without consideration of public comment because it: (1) Allows for the use of the updated version of the standard cited in the Brownfields Law, while also allowing the use of the former version, and the updated version of the standard is similar to, and not significantly different than, the previous standard; (2) reduces the burden of obtaining an appropriate standard, given that the standard cited in the Brownfields Law is no longer available; and (3) this action merely clarifies an interim standard that is effective only until EPA promulgates a final rule replacing the interim standard.

Although we view today's action as noncontroversial, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate proposed rule containing the clarification summarized above. That proposed rule will serve as the proposal to be revised, if adverse comments are received. If EPA does not receive adverse comment in response to this rule prior to February 24, 2003, this rule will become effective on March 25, 2003, without further notice. If EPA receives adverse comment, we will publish a timely withdrawal of this rule in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time and before February 24, 2003.

IV. Future Rulemaking Setting Standards for ''All Appropriate Inquiry''

EPA also is announcing today its progress in developing regulatory standards for conducting ''all appropriate inquiry.'' The Brownfields Law requires that EPA promulgate such standards within two years of enactment of the law, or by January 2004. Congress included in the Brownfields Law a list of criteria that the Agency must address in the regulations establishing standards and practices for conducting all appropriate inquiry (section 101(35)(2)(B)(ii)). The Act also requires that parties receiving funding under the Federal brownfields program to conduct site assessments must conduct the site assessment in accordance with the standards and practices for all appropriate inquiry established under the same provision of the Act.

EPA is soliciting the advice and input of public and private stakeholder groups in developing the regulations for conducting all appropriate inquiry in accordance with the criteria set forth by Congress. We understand that voluntary standards developed by standards developing organizations, such as the ASTM 1527–2000 standard, are available and are currently being used to conduct all appropriate inquiry in conjunction with private real estate property transactions. In addition, site assessment protocols have been established under the Federal Superfund remedial action and RCRA corrective action programs, as well as within State clean up programs. We intend to develop Federal regulations that build upon the depth of experience accrued in both the public and private sectors in implementing these standards and programs. We believe that building upon currently available private sector standards for undertaking all appropriate inquiry as well as building on the experience of state and Federal government site assessment programs is the most efficient and economical way to develop Federal regulatory standards that will both meet the criteria set in the Brownfields Law and ensure minimal disruption to the private market and State and Federal site assessment programs.

To ensure that we obtain a diverse array of input from both private sector stakeholders and state program officials, EPA is developing the federal regulations by soliciting private and public sector input under the convening stage of the negotiated rulemaking process, and may supplement our information gathering through the conduct of public meetings. We initiated the convening stage of a negotiated rulemaking process to identify appropriate stakeholder groups and solicit advice and input from experienced public and private sector users of similar standards. Following an evaluation of stakeholder interests and input during the convening process, we either will announce our intent to continue with a negotiated rulemaking process, or announce our intent to solicit public input, by way of an additional notice or a public meeting, on options for a proposed rulemaking that will set standards for all appropriate inquiry. We anticipate announcing our intended approach for the development of a proposed rulemaking in the **Federal Register** during the winter of 2003. Any questions regarding our future regulatory effort should be directed to the parties listed above in the section entitled **FOR FURTHER INFORMATION CONTACT.**

V. Statutory and Executive Order Reviews

a. 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.

b. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 FR U.S.C. 3501 *et seq.*)

c. The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the APA 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. This action will not have a significant impact on a substantial number of small entities because it does not create any new requirements.

d. Because the purpose of today's action is to make a clarification that does not create any new requirements it has no economic impact and is not subject to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pubic Law 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.

e. 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).

f. This rule does not have tribal implications, as specified by Executive Order 13175 (65 FR 67249, November 6, 2000).

g. This rule is not subject to Executive Order 13045 (62 FR 1985, April 23, 1997), because it is not economically significant.

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

i. This action does involve technical standards; therefore, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) apply. The NTTAA was signed into law on March 7, 1996 and, among other things, directs the National Institute of Standards and Technology (NIST) to bring together federal agencies as well as state and local governments to achieve greater reliance on voluntary standards and decreased dependence on in-house standards. It states that use of such standards, whenever practicable and appropriate, is intended to achieve the following goals: (a) Eliminate the cost to the government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation; (b) provide incentives and opportunities to establish standards that serve national needs; (c) encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and (d) further the policy of reliance upon the private sector to supply Government needs for goods and services. The Act requires that federal agencies adopt private sector standards, particularly those developed by standards developing organizations (SDOs), wherever possible in lieu of creating proprietary, non-consensus standards. Today's action is compliant with the spirit and requirements of the NTTAA, given that the interim standard for all appropriate inquiry that is the subject of today's action is a private sector standard developed by a standard developing organization. Today's action allows for the use of the American Society for Testing and Materials (ASTM) standard known as Standard E1527–2000 and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process'' as the interim standard for conducting all appropriate inquiry for properties purchased on or after May 31, 1997, or in the alternative, the use of Standard E1527–97, and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.''

j. Today's action does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

k. 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 submitted 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 March 25, 2003 unless EPA publishes a withdrawal in the **Federal Register**.

List of Subjects in 40 CFR Part 312

Environmental protection, Administrative practice and procedure, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 17, 2003.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, title 40 chapter J of the code of Federal Regulations is amended as follows:

1. Title 40 Chapter J is amended by adding new part 312 to read as follows:

PART 312—INNOCENT LANDOWNERS, STANDARDS FOR CONDUCTING ALL APPROPRIATE INQUIRY

Subpart A—Introduction

Sec.
312.1 Purpose and applicability.
312.2 Standards and practices for all appropriate inquiry.

Subpart B—[Reserved]

Authority: Section 101(35)(B) of CERCLA, as amended, 42 U.S.C. 9601(3)(B).

Subpart A—Introduction

§ 312.1 Purpose and applicability.

(a) *Purpose.* The purpose of this section is to provide standards and procedures for ''all appropriate inquiry'' for the purposes of CERCLA section 101(35)(B).

(b) *Applicability.* This section is applicable to: potential innocent landowners conducting all appropriate inquiry under section 101(35)(B) of CERCLA; bona fide prospective purchasers defined under section 101(40) of CERCLA; contiguous property owners under section 107(q) of CERCLA; and persons conducting site characterization and assessments with the use of a grant awarded under CERCLA section 104(k)(2)(B)(ii).

§ 312.2 Standards and practices for all appropriate inquiry.

(a) With respect to property purchased on or after May 31, 1997, the procedures of the American Society for Testing and Materials (ASTM)1527–97 and the procedures of the American Society for Testing and Materials (ASTM) 1527–2000, both entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process,'' shall satisfy the requirements for conducting ''all appropriate inquiry'' under section 101(35)(B)(i)(I) of CERCLA, as amended

by the Small Business Liability Relief and Brownfields Revitalization Act.

[FR Doc. 03–1631 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3050–F]

RIN 0938–AK40

Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires hospitals to develop and maintain a quality assessment and performance improvement (QAPI) program. In the December 19, 1997 **Federal Register**, we published a proposed rule to revise the hospitals conditions of participation (CoPs). The QAPI CoP was one of the conditions included in the proposed rule. We separated the QAPI CoP from the larger set of hospital CoPs so that it could be published in advance of the remaining CoPs to implement the Administration's initiatives regarding medical errors. QAPI focuses provider efforts on the actual care delivered to patients, the performance of the hospital as an organization, and the impact of treatment furnished by the hospital on the health status of its patients. Specifically, it is important to note that a QAPI is not designed to measure a hospital's quality, but rather a minimum requirement that the hospital systematically examine its quality and implement specific improvement projects on an ongoing basis. State agencies (SAs) during their surveys, review all aspects of a hospital's operations and this review provides a framework in which the SA can assess a hospital's QAPI program. In addition, the QAPI entails all activities required for measuring quality of care and maintaining it at acceptable levels. This typically includes—

- Identifying and verifying quality-related problems and their underlying cause;
- Designing and implementing corrective action activities to address deficiencies; and
- Following up to determine the degree of success of an intervention and to detect new problems and opportunities for improvement.

Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.

EFFECTIVE DATE: These regulations are effective on March 25, 2003.

FOR FURTHER INFORMATION CONTACT: Nancy Archer, (410) 786–0596; Mary Collins, (410) 786–3189; Monique Howard, (410) 786–3869; Jeannie Miller, (410) 786–3164;

SUPPLEMENTARY INFORMATION:

I. Background

A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' to revise the entire set of Conditions of Participation (CoPs) for hospitals. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

B. Patient Safety and Medical Errors

In 1999, the Institute of Medicine (IOM) published a report entitled ''To Err is Human: Building a Safer Health System,'' which highlighted patient injuries associated with medical errors. In this report, the IOM defined an error as the following: ''An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.'' The IOM report also indicated that an estimated 44,000 to 98,000 Americans die annually as a result of preventable medical errors. The results of the report have generated substantial media, public, Congressional, and Departmental concerns regarding patients health and safety.

As recommended by the IOM, the Quality Interagency Coordination Task Force (QuIC), evaluated and responded to the recommendations in the IOM report with a strategy to identify patient safety issues and to reduce the number of errors by 50 percent over the next 5 years. In an effort to thoroughly consider all of the relevant issues related to medical errors, the QuIC expanded the IOM's definition to read as follows: ''An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.'' We have adopted the QuIC revised definition of an error.

Accordingly, the QAPI CoP has been separated from the larger set of CoPs and published in an accelerated timeframe because it provides the framework to implement the Administration's initiatives designed to help distinguish and avoid mistakes in the healthcare delivery system. In addition, we are requiring that a hospital's QAPI program be an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. The remaining provisions of the hospital CoPs will be published at a later date.

Many people believe that medical errors involve medication (for example, an incorrect or improper dosage of medicine) or surgical errors (for example, incorrect site amputation). However, there are many other types of medical errors including—

- Diagnostic errors (for example, misdiagnoses leading to an incorrect choice of therapy or treatment, failure to use an indicated diagnostic test, misinterpretation of test results, and

failure to properly act on abnormal test results);

- Equipment failures (for example, a defibrillator without working batteries, or inadvertent dosing of medications in a short time frame due to intravenous pumps with valves that are easily dislodged);
- Infections (for example, nosocomial and post-surgical wound infections);
- Blood transfusion-related injuries (for example, hemolytic blood transfusion reactions); and
- Deaths due to seclusion or restraint use.

Harm experienced while receiving healthcare services is a growing concern for the American public. While both the public and the private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed to further reduce these types of incidents. Therefore, we are publishing this final rule, with some modification in response to comments, to guide improved patient safety in the hospital setting.

Medical errors can be difficult to recognize in healthcare due to the variations in individuals' responses to treatment. In addition, medical professionals may not recognize that a particular product or procedure may have contributed to or caused a problem since the patient is already ill or the event appears unrelated to the product or procedure. Because medical errors usually affect only a single patient at a time, they are treated as isolated incidents and little attention, if any, is drawn to these problems. Finally, the healthcare community acknowledges that errors are most likely under reported due to malpractice threats and practitioner confidentiality concerns. All of these factors explain the ongoing invisibility of medical errors despite the existence of research that documents their high prevalence. The IOM report recommended the following:

- Action to reduce preventable medical errors;
- Implementation of a system of public accountability;
- The development of a knowledge base system regarding medical errors; and
- A culture change in healthcare organizations in order to promote the recognition of errors and improve patient safety.

C. Balancing Collegial and Regulatory Modes of Oversight

The proposed revision of the hospital CoPs is part of a larger effort to bring about improvement in the quality of care furnished to beneficiaries through a patient-centered approach to healthcare delivery, quality improvement, and integration of care, as well as our quality of care oversight responsibilities.

The fundamental purpose of the QAPI CoP is to set a clear expectation that hospitals must take a proactive approach to improve their performance and focus on improved patient care. We stress improvement in systems in order to improve processes and patient outcomes. This is not meant to suggest that we plan to abandon our regulatory role. In fact, this approach reinforces our primary responsibility for assuring patient safety and protection through our delegated regulatory authority.

We must note that accreditation surveys for deemed status performed by JCAHO, AOA, and any other national accrediting organization recognized by us in the future, are performed under an extension of our authority. Onsite accreditation surveys may serve as the basis for enforcement activity since accreditation organizations' standards are determined by us to meet or exceed our own CoPs. SAs acting as our regulatory agents perform validation, recertification, and complaint surveys in hospitals to determine compliance with the CoPs.

During surveys the QAPI program will be evaluated for its hospital-wide effectiveness on the quality of care provided. The impact of the program will be assessed during a survey, as surveyors are looking at data gathered at different points in time, compared, and actions taken based on that comparison. The hospitals will be analyzing data and evaluating the effectiveness of their own program continually.

Whenever the state agency surveyors enter the hospital to conduct a survey they will evaluate the hospital's program and its own internal evaluation process along with an evaluation of all hospital services. When there is an onsite review of the hospital's QAPI program, the surveyors determine whether or not the hospital is meeting the QAPI CoP requirements. Following the existing survey process and procedures, if the SA determines that the hospital is significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs. The hospital is then given the opportunity to submit a plan of correction. The SA would conduct a follow-up survey to assess whether the hospital is now in compliance with all of the requirements, prior to the actual termination taking place.

Three to five years after the implementation of this final rule, we will assess Online Survey Certification and Reporting System (OSCAR) data and evaluate how well hospitals have implemented the QAPI process. During this time, we will also assess the state of the art for quality improvement practices.

Similarly, we view the Quality Improvement Organizations (QIOs) (formally known as Peer Review Organizations (PROs)) operating in a largely ''penalty-free'' environment, as our quality improvement agents. Each State has a QIO that contracts with Medicare to monitor and improve the care delivered to beneficiaries. Each QIO operates under a contract know as a ''statement of work'' governed by extensive portions of Titles 11 and 18 of the Act, as amended by the Peer Review Improvement Act of 1982. Specific QIO tasks fall under three areas of responsibility, as provided in the Act and reiterated in the statement of work:

- Improve quality of care for beneficiaries by ensuring that beneficiary care meets professionally recognized standards of health care;
- Protect the integrity of the Medicare trust fund by ensuring that Medicare only pays for services and items that are reasonable and medically necessary and that are provided in the most appropriate (for example, economical setting);
- Protect beneficiaries by expeditiously addressing individual cases, such as beneficiary complaints, provider-issued notices of noncoverage, Emergency Medical Treatment and Active Labor Act (EMTALA) violations and other statutory responsibilities.

We look to the QIOs to advance quality of care in the hospital environment. We view accreditation deeming activities as part of our overall responsibility to certify providers for program participation.

II. Legislation

Section 1861(e)(1) through (9) of the Act: (1) Defines the term ''hospital''; (2) lists the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in the regulations 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. Under section 1865 of the Act and 42 CFR 488.5 of the regulations, hospitals that are accredited by the JCAHO or the AOA are not routinely surveyed by SAs for compliance with the CoPs but are

deemed to meet most of the requirements based on their accreditation.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. The regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

III. Provisions of the Proposed QAPI CoP

We proposed revisions of the CoPs that emphasized lessening Federal regulation: (1) To eliminate unnecessary structural and process requirements; (2) focus on outcomes of care; (3) allow greater flexibility to hospitals and practitioners to meet quality standards; and (4) place a strong emphasis on quality assessment and performance improvement.

The proposed provisions of the QAPI CoPs included three standards that addressed the scope and direction of the performance improvement program, discussed the hospital entity that is responsible and accountable for the QAPI activities, and retained the current requirement on autopsies (existing § 482.22(d)). In addition, we proposed 12 critical areas in which hospitals must, at a minimum, objectively evaluate their performance.

We solicited comments on the feasibility of national outcome-based performance measures for hospitals and the minimum level requirements for performance improvement activities. We did not include in the hospital CoPs any requirement for hospitals to collect and report certain standard data items that could produce quality of care predictors in the future. However, we did invite public comment on the following seven key questions regarding the development and implementation of hospital-based performance measures.

(1) Should CMS assume a leadership role in developing the measures?

(2) How should CMS proceed to develop and implement the measures?

(3) If CMS does not assume a leadership role in this area and hospitals invest in the development of multiple systems, would the overall burden be greater than if a single system had been imposed at the outset?

(4) If CMS does not assume a leadership role in this area and individual hospitals adopt multiple systems that produce nonstandardized data, to what extent would it be difficult to make comparisons between hospitals?

(5) Should CMS require or encourage hospitals to use the standardized measures that some accredited hospitals are using?

(6) Would it be appropriate for CMS to include ''placeholder'' language in the revised CoPs concerning the eventual need for hospitals to report relevant data, or is this premature?

(7) If CMS includes ''placeholder'' language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

IV. Analysis of and Responses to Public Comments

We received over 1,200 comments in response to the QAPI requirements presented in the December 19, 1997 proposed rule. These comments were from hospitals, professional organizations, accrediting bodies, practitioners, and other individuals. Summaries of the public comments received and our responses to those comments are set forth below.

A. Regulatory Approach

We asked for comments on the fundamental shift in our regulatory focus for quality from the current approach that identifies and corrects problems in patient care delivery to an approach that emphasizes improving patient outcomes and satisfaction using a data-driven QAPI program.

Comment: The majority of commenters expressed support for our change in philosophy and the introduction of the new QAPI CoP, stating this approach will create more consistency between accrediting and regulatory bodies' standards.

Response: We appreciate the support. One of our initiatives is to revise many of the provider CoPs, including hospitals, so that they focus on outcomes of care and eliminate unnecessary procedural requirements.

Comment: A commenter requested clarification regarding whether this requirement applies to all patients or only Medicare patients.

Response: This requirement as well as all of the other hospital CoPs applies to all Medicare- and Medicaid-participating hospitals; therefore, all patients receiving services provided by these hospitals are protected by this requirement. Moreover, these standards govern quality of care issues for the hospital and its practitioners and contractors.

Comment: Many commenters were against promulgating a final regulation that is too prescriptive. They emphasized that what is needed, above all, is flexibility to design a program that meets the needs of hospitals of varying sizes and specialties, rather than a ''one-size-fits-all'' regulation.

Response: We agree and believe that the proposed QAPI condition was designed to incorporate flexibility with the appropriate amount of accountability. We have made several revisions to the QAPI condition, to increase its flexibility and accountability, and minimize burden.

Comment: Some commenters stated that the proposed QAPI condition is process-oriented and conflicts with our intent of reducing process-oriented requirements. In addition, the commenters stated that we should allow hospitals to pursue quality improvement in whatever manner they choose.

Response: We recognize that by permitting hospitals to evaluate themselves in the 12 specific areas we believe are critical to hospital performance, the proposed QAPI appeared prescriptive in nature. Based on public comments, we have deleted the proposed requirement for hospitals to assess their performance in 12 specific areas. We agree that hospitals should be able to pursue quality improvement in a manner of their choosing. We encourage hospitals to identify and resolve performance problems specific to their situations in the most effective and efficient manner possible. The provisions also require collaboration between all hospital departments and services, to ensure that all entities are included, to the greatest extent possible, in the QAPI program. After monitoring, tracking, and assessing performance in all areas of hospital service and operations, the hospital has the flexibility to design a program to address its specific needs. We also believe giving the hospital flexibility to design its own program provides the hospital with the flexibility to adopt its own best practices in specific areas, (for example, hospital staff education, record reviews, and information technology). We believe that it is critically important that hospitals examine the adequacy of their information technology and identify opportunities to improve and expand the use of such technologies to prevent medical errors and improve quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (for example, bar coding and computerized physician order entry systems) in health care settings.

Comment: Some commenters were concerned that our proposal to have an outcome-oriented and patient-centered regulatory approach would eliminate structure and standardized practice

patterns and ultimately jeopardize patient safety.

Response: We did not intend to suggest that hospitals eliminate the standardization of care when appropriate and effective. We believe that one of the most effective means of reducing errors is by standardizing processes wherever possible. For example, by standardizing drug doses and times of administration, the advantages in efficiency as well as in error reduction are obvious. By mandating a QAPI CoP that focuses on performance improvement activities, we expect hospitals to conduct systematic internal QAPI activities including the application of standards of care and best practices throughout the institution. For example, if standardizing insulin coverage sliding scales in the intensive care unit decreased the incidence of hypoglycemia by 25 percent, we would expect the hospital to determine other areas that would benefit from the standardized approach. After making this determination, hospitals should implement and track actions and determine a mechanism to assure achievement of goals and sustained improvement.

Comment: A commenter suggested strengthening the regulation text by adding the phrase ''hospital-wide'' as used in the preamble.

Response: We agree with the commenter and have made the appropriate changes to § 482.21. The change in language recognizes the importance of assuring that the QAPI program reflects the complexity of the hospital's organization and services.

Comment: Some commenters believed that medical staff provisions should not be deleted as they are not entirely captured in this QAPI provision.

Response: In the December 19, 1997 proposed rule, we proposed to eliminate several process-oriented requirements, currently set forth in §§ 482.12 and 482.22, relating to the composition, organization, and conduct of a hospital's medical staff. We have decided to defer any decision regarding the proposal to delete these requirements until the remaining hospital CoPs are published in their entirety.

B. Other QAPI Approaches

We solicited comments on other possible approaches to the QAPI condition to ensure that hospitals invest substantial effort in QAPI. In addition, we solicited comments on how we might offer a more precise explanation of our expectations.

Comment: Several commenters made recommendations for more precise ways to measure performance. One commenter suggested that we use historical billing data to establish minimum benchmarks or standards of performance as a basis for the performance-based reimbursement system, stating that financial incentives are the best way to motivate change and improve performance. Other commenters stated that a combination of outcome data and the assessment of structured quality improvement processes would be more effective. However, most commenters overwhelmingly expressed concerns that we should develop a final requirement that would allow for flexibility.

Response: We appreciate the commenters' suggestions for more precise ways to measure performance but we believe that these suggestions are more prescriptive than the proposed strategy. In addition, we currently do not have a basis or statutory authority for a performance-based reimbursement system based on benchmarks developed from historical billing data. We agree that using outcome data in combination with assessing the structure of the QAPI program and processes of the hospital would be very effective. However, standardized outcome measures that can be used nationwide have not been established to date so this is not feasible at this time. We believe that the QAPI requirements presented in this final rule address the flexibility concerns of the majority of commenters.

Comment: Several commenters suggested creating a transition period in order to ease the burden of creating a QAPI program.

Response: Since hospitals are currently required to have an ''effective, hospital-wide quality assurance program'' in accordance with § 482.21, we do not believe a transition period is necessary.

Comment: Many commenters stated the proposed QAPI requirements will substitute high-level hospital-wide QI processes for more effective, focused, department-level performance improvement. These commenters suggested strengthening the language by adding sentinel events to the minimum performance elements.

Response: We agree that hospitals should consider adverse events in the development of its QAPI strategy. We expect hospitals to implement an internal error reduction system. Adverse event tracking and analysis of underlying causes are an effective way to determine issues involving medical errors. We emphasize the need for hospitals to assess processes and systems that affect patient care and quality. Section 482.21(c) requires the hospital(s) to establish priorities, and identify areas of risk that affect patient safety. We believe that the identification of adverse events and analyses of events must be an integral part of the hospital's QAPI program, as the analyses will lead to better protections for patients.

JCAHO's performance improvement strategy is consistent with our approach. Their standards require hospitals to collect data to monitor performance of processes that involve risks or may result in sentinel events. Similarly, § 482.21(c) requires hospitals to consider prevalence and severity of identified problems and to give priority to improvement activities that affect clinical outcomes, patient safety, and quality of care. In order to meet the requirements, a hospital should consider information from its own risk-management data or from external sources of information (for example, hospital industry data on problem-prone processes, JCAHO's list of frequently occurring sentinel events; data from the National Patient Safety Foundation) and quality indicators from the Healthcare Cost and Utilization Project (HCUP QIs), as possible data measures to assist hospitals in designing their QAPI programs pertinent data and information from our ''science partner'' the Agency for Healthcare Research and Quality (AHRQ) (*http://www.arhq.gov/data/hcup/qiact.htm*).

C. Minimum Elements for a QAPI Program

We proposed that the hospital's QAPI program consist of assessment activities in a minimum of 12 areas. We also asked for comments on the minimum content of the QAPI program.

Comment: We received many comments citing concerns in the medical community about the broad language of the proposed rule regarding minimum performance areas and associated projects, and the possibility that it could be interpreted to mean that hospitals must perform 12 simultaneous projects. Commenters stated that projects in all areas would be too prescriptive and burdensome, and suggested allowing hospitals to prioritize and implement improvement activities based upon self-assessment. It was stressed that small hospitals would have difficulty identifying measures predictive of outcomes in all 12 areas and low patient volumes in rural hospitals would produce data of little value.

Response: We proposed 12 specific areas of self-assessment, which we believe are critical to a hospital's evaluation of its performance. However, we gave serious consideration to

commenters' concerns regarding burden and the misunderstanding of the self-assessment in the 12 areas and have eliminated this requirement. In this final rule, although we have not specifically prescribed areas to be assessed, the CoP requirement is for the hospital's QAPI program to be, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. Section 482.21(c) requires that hospitals set priorities for performance improvement based on the prevalence and severity of identified problems. Hospitals are expected to assess all areas of hospital services and operations, and based on that information prioritize the improvement activities that most directly affect patient safety and clinical outcomes. The most important aspect of a QAPI program is the implementation of actions based on the hospital's assessment of its improvement needs. The hospital must use the data collected and make changes in its processes or programs to improve patient outcomes. When adverse outcomes are identified, hospitals must, when applicable, perform system and process analyses and take action to achieve and sustain long-term corrections. These actions could include changes in protocols and systems and staff education and training.

We recognize the special needs and circumstances of rural hospitals. We also recognize that the collection and analysis of clinical outcome data could represent some increase in burden on some hospitals, particularly on the nonaccredited hospitals that are subject to our survey process. Nonaccredited hospitals typically are smaller than most accredited hospitals, are located in sparsely populated areas, and may not have the resources for extensive data gathering and reporting. For these reasons, the framework established by the QAPI CoP is flexible enough to recognize the unique circumstances and characteristics of hospitals. The QAPI CoP affords the hospital the flexibility to identify processes targeted for improvement based on its unique needs, priorities and patients. Hospitals that have more resources may be able to produce more sophisticated measures that involve more complex issues, but the focus for all hospitals is that they make an aggressive and continuous effort to improve performance and address patient safety issues. Moreover, we would expect the processes targeted for improvement to change over time as the hospital succeeds in its initial efforts.

Comment: Some commenters agreed with our rationale for the inclusion of these areas stating these can point to opportunities for improvement in both hospital and practitioner performance.

Response: Although we agree that our rationale for listing these 12 areas represent identifiable opportunities around which a hospital could develop a QAPI program, we determined that a far more valuable approach, at this time, would be to allow hospitals the flexibility to identify their own areas to address. Characteristics of healthcare delivery are too diverse and hospitals strengths and weaknesses are too varied to take such a narrow approach.

Comment: We were asked to clarify how a hospital would show sustained improvement in all 12 areas, anticipating it would be too difficult to select measures to guarantee and improve patient outcomes.

Response: As stated above, we have eliminated the 12 areas presented in the proposed rule. One of the benefits of operationalizing a QAPI program is that, because it is a continuous process, it affords the hospital a mechanism for evaluating its own improvement efforts. Specifically, the process of improvement includes—

- Identification of an organization's critical patient care and services components;
- Application of performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services; and
- Continuous use of a method of data collection and evaluation that identifies or triggers further opportunities for improvement.

Comment: Commenters requested that we clarify and define the list of 12 areas, but the overwhelming majority of commenters strongly encouraged the deletion of the list. These commenters argued it would be more effective to allow hospitals to assess, measure and analyze themselves, but concurred with the identification of hospital processes and functions that could produce valuable information. Alternatives were given such as the adaptation of JCAHO's standards, or us merely providing the components of the QAPI program and giving the hospital the flexibility to create a program of its own design.

Response: As stated previously, we have eliminated the list of 12 areas for self-assessment. The regulations provide the components of a QAPI program and allow for individual hospital flexibility in implementation.

Comment: Some commenters suggested that nonaccredited hospitals be exempt from QAPI requirements until we provide scientific evidence that participation in external measurement systems by nonaccredited hospitals improves patient care.

Response: We cannot relinquish our responsibility for assuring quality healthcare to all patients. We believe that we have provided hospitals with enough flexibility and have identified enough resources for improving the process of patient care to facilitate the development of an effective QAPI program by a hospital of any size. Therefore, we do not believe there is a need to differentiate our expectations for accredited and nonaccredited hospitals.

D. Data

We proposed that hospitals use hospital-specific data (for example, medical record and committee information), including QIO, and other relevant data as an integral part of its QAPI program. In this final rule under § 482.21(b), program data, we use the phrase ''quality indicator data including patient care data, and other relevant data,'' since hospital-specific data, is covered under ''other relevant data.'' The infrastructure of performance improvement activities is based on the collection of data. Analysis of this data allows hospitals to identify trends, identify process variations, and assess performance patterns. We recognize there may be some costs associated with data collection, and realize it is not feasible nor desirable to collect data on everything. Therefore, we have given the hospital the flexibility to establish, through its priorities and needs, the areas on which to focus. Data collection should focus on areas of prevalence and the severity of identified problems, giving consideration to patient safety and quality of care. The governing body must determine priorities regarding which processes to monitor with data collection and the subsequent development of planned improvement efforts, as needed.

E. Improvement Projects and QIO Projects

In the preamble to the proposed rule, we asked whether we should require a hospital to engage in a minimum number of improvement projects that are based upon their own performance assessments. In the proposed regulation text, we stated that hospitals must track performance to assure that improvements are sustained. We asked for comment on the advisability and necessity of such a requirement, and

also on the best approaches to achieve this minimum level of effort. We also proposed that if a hospital chooses not to participate in a QIO project, it must be able to demonstrate, to the SA, a level of achievement through its own QAPI strategy comparable to or better than expected from QIO participation.

Comment: A commenter stated QAPI should not be required without the supporting scientific evidence showing QAPI improves patient care.

Response: The current quality assurance CoP (§ 482.21) has been in effect since 1986. At that time the healthcare industry as a whole embraced a quality assurance approach to measuring and improving the care delivered to patients. The 1986 CoP reflected state-of-the-art practices. Since that time, the healthcare industry has moved toward a QAPI approach in the delivery and measurement of patient care. The proposed rule was intended to update the existing quality assurance CoP to reflect current practice in quality improvement. We proposed to change the focus of a hospital's quality assurance activities from one that relies on a problem-focused approach of quality assurance to one that focuses on systemic quality improvements, that parallels the JCAHO's overhaul of its accreditation standards.

We specifically requested public comment on the approach as well as the advisability and necessity of the proposed requirements. Commenters were in favor of and supported the continuance of the existing quality assurance CoP. However, they were overwhelmingly opposed to the proposed QAPI requirement that mandated assessment in 12 predetermined areas, stating that this was too rigid and prescriptive.

As stated earlier, we restructured the final rule based on public comments and have eliminated the proposed provision requiring assessment in 12 predetermined areas. We believe that this final rule gives the hospital the flexibility to establish a QAPI program that meets our requirements by conducting systems or process analysis and taking actions to afford long-term correction and improvement of identified or potential problems.

Comment: Several commenters stated that the final regulation should specify both a minimum level of scope, as well as a minimum number of improvement projects. One commenter added the number of improvement projects required should be based on the percentage of all patients receiving services at the hospital. Conversely, the overwhelming majority of commenters were strongly against any such requirement, favoring an approach where the hospital would be required to demonstrate to the SA what projects they are doing and what progress is being achieved.

Response: We considered specific requirements regarding the number, scope, and complexity of projects to be performed by each hospital. In the preamble of the proposed rule, we specifically stated that at a minimum, we were considering requiring that the number of distinct successful improvement activities to be conducted annually be proportional to the scope and complexity of the hospital's programs and we also presented other alternatives for consideration. We decided not to base the number of projects on discharges, number of beds, or operational areas as proposed. Based on public comments, we have decided to require hospitals to document what quality projects are being conducted, the reasons for conducting these projects, and measurable progress achieved on these projects. In fulfilling the QAPI regulatory requirements for collection and use of clinical data, we anticipate that hospitals will make use of information technologies. Indeed, we believe that the effective use of information technology (IT) systems (for example computerized physician order entry systems (CPOE) or barcoding) could over time prove invaluable to the improvement of quality and safety of patient care. As an alternative to a performance improvement project, we added a provision, § 482.21(d)(2), that allows hospitals to invest in information technology; that is, we will allow hospitals to undertake a program of investment and development of IT system that are geared to improvements in patient safety and quality, in place of a QAPI project. In recognition of the time required to develop and implement this type of system, we will not require that such activities have a demonstrable benefit in their initial stages, but we would expect that quality improvement goals and their achievement would be incorporated in the plan for the program. Initial stages of development, include activities such as installation of hardware and software, testing of an installed system, training of staff, piloting the system, and hospital-wide implementation of the system. Upon implementation of the system, monitoring will begin and data will be collected over time as part of the process to evaluate the impact of the new system on patient safety and quality. We believe that this modification demonstrates this Administration's deep commitment to patients, high quality care, and flexibility to our partners. This approach will allow hospitals the flexibility to invest appropriate efforts in their quality program and the freedom to make decisions about the best way to improve the quality of care.

Comment: A commenter stated that we have failed to identify the specific outcomes hospitals should achieve, measure, and report. The commenter advocated uniform, standardized measures.

Response: Our long-term goal is the identification of a standardized measure set for hospitals. However, since these measures have not yet been identified, we expect hospitals to engage in activities based on analyses of their own data, initiatives that promote patient safety, improve quality of care, and increase patient satisfaction. One goal of this rule is to stimulate providers to develop and pursue a wide variety of information and data, from internal and external sources, to guide their improvement efforts. External sources of information and data can include organizations like the National Quality Forum (NQF), QIOs, and accrediting bodies.

Comment: Commenters agreed with the concept of performance improvement, but stated most aspects of quality depend on judgments and subjective assessments. These commenters questioned if quality improvement would be quantified into numerical values, and if so, what numerical value would demonstrate optimum performance, and what should be done if that level is not achieved.

Response: Through our survey process, we intend to assess the hospitals' success in using its own objective data, assessing performance, prioritizing improvement efforts, and demonstrating that sustained improvements have taken place. In the future, based on a set of standardized performance measures that can be used nationwide, some improvement efforts might by quantified into numeric values. However, as stated in the 1999 IOM report, continuous improvement assumes there is no threshold for good performance. The central premise is that healthcare systems should never be content with present performance. Rather, providers of healthcare services should continuously study and improve the process of healthcare and service delivery.

Comment: One commenter proposed a revision to the following requirement: The hospital must take actions that result in performance improvements and must track performance to assure that improvements are sustained. The

commenter proposed the requirement should read: ''The hospital must take quality assessment and improvement actions that result in improved performance outcomes for identified problems.'' Several other commenters wrote seeking clarification regarding the meaning of the phrase, ''improvements that are sustained.''

Response: We did not accept the commenter's proposed language verbatim, but we did modify the language. The evaluation should enable a facility to judge where resources need to be focused for priority improvement efforts, while assuring sustained improvement in areas where improvement goals have been achieved. For example, if project(s) to improve reduction in antimicrobial resistance have produced successful improvements in the physician's antibiotic prescribing patterns and in the facility's anti-microbial resistance rate, a hospital might defer funding for this effort to focus on another priority topic. At the same time, success with the first project must be sustained, and where possible, improved further over time. Lessons learned from past projects should be incorporated into staff training and evaluations, where appropriate. The evaluation ''loop'' of setting priorities for improvement, tracking results and determining continued use of resources based on priorities must include continued evaluation of outcomes in ''past'' improvement projects and staff education in a manner determined by the facility. These activities should lead to long-term correction and improvement of identified focus areas.

Comment: A commenter stated that not all hospital departments and services, for example marketing and maintenance, should be included in QAPI programs. The commenter also recommended that the language of the requirement be changed to delete the word ''all.''

Response: We did not accept the commenter's suggestion to delete the word ''all.'' We believe that all hospital departments and services furnished under contract or arrangement, must be involved in the hospital-wide QAPI program. The hospital's marketing program may be instrumental in increasing patient satisfaction and performing post-hospital surveys. The hospital's maintenance program may be instrumental in decreasing the potential for infections. There are many ways to involve all areas of the hospital. This final rule, although flexible, requires hospitals to consider the entire scope of its services and operations. However, we reiterate that although a hospital is required to monitor and track performance in all areas of its operations, it must use this surveillance activity to help set priorities for the remainder of its QAPI program including data collection, development of performance measures, and the selection of specific quality improvement projects.

Comment: The overwhelming majority of commenters wrote that not all QIO data is relevant and timely and sought clarification regarding how a hospital choosing not to participate in a QIO project would demonstrate that its own QAPI strategy is comparable to or better than that expected from QIO participation. Some commenters requested clarification regarding demonstrating ''value,'' as well as the determination of a ''sufficient'' project.

Response: We share the commenters'' concern and as a result, we are revising the proposed regulation text, now § 482.21(d)(4) of this final rule, to require projects of comparable effort. Through our QIOs, we are working to reduce errors of omission for 39 million Medicare beneficiaries. Under their current performance-based contracts, QIOs are working to prevent failures and delays in delivering services for breast cancer, diabetes, heart attack, heart failure, pneumonia, and stroke. These efforts have already decreased mortality for heart attack victims. In assessing projects, hospitals should consider the number of patients affected, range of services covered, the projected magnitude of the benefit to individual patients, as well as the actual changes achieved by the project versus the actual changes achieved by participants in the QIO project. Any improvements in care made by hospitals working with the QIOs on their projects would transfer to better care and services to all patients served by these hospitals. Although hospitals are not required to participate in QIO projects, the hospital must document what quality projects are being conducted, the reason for conducting these projects, and that the measurable progress achieved on these projects demonstrate that the projects are of comparable effort. A hospital can compare its own projects to QIO cooperative projects if the following techniques are used as guidance:

- Improvement Projects—These projects are based upon the hospital's own assessments of its performance and show measured, sustained results that actually benefit patients. Because most organizations identify more improvement opportunities than they can initiate, improvement project priorities have to be set. These priorities must be endorsed by the hospital's governing body. Although we do not require a specific number of projects, we do expect the number of distinct improvement projects conducted annually to be proportional to the scope and complexity of the hospital's program. JCAHO states in its Comprehensive Accreditation Manual for Hospitals that certain criteria—the expected impact on performance; and the selection of a high-risk, high-volume, or problem-prone process to monitor— are helpful in setting project improvement priorities. We are adopting a parallel philosophy by specifying at § 482.21(c) that a hospital must prioritize its performance activities, which must focus on high-risk, high volume, or problem-prone areas; consider the incidence, prevalence, and severity of the problem in those areas; and affect clinical outcomes, patient safety, and quality of care. Therefore, we are giving the hospital the flexibility to determine the areas that require performance projects.
- Quality Improvement Organization Projects—There are two basic areas of consideration used when establishing criteria for selection of QIO projects: identifying clinical topics and prioritizing clinical topics. These criteria were designed to ensure that a project has the greatest likelihood of significantly impacting the health outcomes of Medicare beneficiaries. Hospitals should utilize these same criteria in determining which projects best encompass the needs of their particular hospital, and in determining if projects identified by the hospital would be comparable to the expected outcomes of those identified by their QIO.

Comment: Many commenters understood that the proposed requirement would mean that hospitals would have to demonstrate they are doing as ''good of a job'' as a QIO if they chose not to participate in QIO projects. These commenters, however, stated that this process would be burdensome for hospitals, and would be counterproductive to the goal of establishing positive cooperative relationships.

Response: We disagree. The requirement is to demonstrate a comparable effort. Since the requirement is to invest equal effort, the following material is included as guidance only as how to better make these decisions.

There are four criteria that QIOs use to assess when identifying clinical topics: prevalence, science, measurability and the opportunity to improve care. These criteria address the

issues central to identifying appropriate clinical topics and quality indicators. The remaining criteria are relevant in establishing priorities among those clinical topics that meet the first four criteria (essentially, determining how you can best allocate limited resources to obtain the greatest improvement for the most beneficiaries). We are providing additional guidance regarding the use of criteria for identifying clinical topics as follows:

• Prevalence, Incidence and Disease Impact—The burden (morbidity, mortality) of the clinical condition or medical procedure under consideration is great for the population affected. The burden within a subpopulation (for example, minority, disabled, at-risk) may be another consideration that is taken into account.

• Science—There should be scientific consensus through multiple independent observations or clinical trials that changing a process or procedure of care will measurably improve patient outcomes. Note that we are adopting the operational definition of the term ''scientific consensus'' by the Office of Medical Applications of Research in the Office of the Director of the National Institutes of Health as follows:

* * * (T)he (consensus) statement reflects the unified view of a panel of thoughtful people who understand the issues before them and have carefully examined and discussed the scientific data available on these issues. The creative work of the panel is to synthesize this information, along with sometimes conflicting interpretations of the data, into clear and accurate answers to the questions posed to the panel.

• Measurability—The process(es) or outcome(s) of care for the topic can be stated in clearly defined, discrete, and quantifiable data elements from data sources which are valid and reliable; accessible in a timely manner; from appropriate care settings; and when necessary, span the continuum of care. In addition to the final measures of outcome, interim measures of progress toward achieving the quality improvement goal are desirable.

• Opportunity to Improve Care—Not only should the process or outcome be measurable, there should be a gap between current performance and what can reasonably be achieved. The wider the gap between the present situation and what is feasibly achievable, the greater the opportunity is for improvement. Additionally, there must be a feasible means of narrowing that gap. Merely measuring the problem is not sufficient; you must also be reasonably certain your actions can improve the situation.

Clinical topics meeting the above criteria should be further prioritized. The following criteria should be helpful in that process. Although it is likely that no topic will consistently meet all of the criteria, proposed topics can be compared on the basis of the number and degree to which the criteria are met.

• Previous Projects or Pilot Studies—Demonstrate or provide a citation that demonstrate previous experience with the proposed project methodology or demonstrate that a project of similar design can reasonably be expected to improve healthcare outcomes. Potential priority topics may have been the subject of previous successful projects by QIOs or other organizations. Here, the focus is on selecting topics for which quality improvement has previously been demonstrated or on replicating successful project methodologies.

• Adequate Program Resources—Consider whether you have adequate resources (time, personnel, and funding) to implement the quality improvement project. Alternative potential projects with similar costs should be compared for their relative potential benefit. Whenever feasible, topics that make use of existing data sets should be selected.

• Availability of Partnerships—Select topics that allow you to collaborate with other providers and national, regional, and local organizations with similar goals. Collaboration with other organizations is encouraged for several reasons: planning, implementation, and analytic costs can be shared; planned, coordinated differences in project methods can be compared for efficacy and cost; local lessons learned can be shared and compared; and ideas for second and subsequent improvement cycles can be gathered.

• Ability to Enable or Facilitate Ongoing Quality Improvement—Select topics and interventions that are likely to foster or enhance the development of quality improvement efforts which extend to care processes and conditions beyond those targeted by the improvement project. Some topics may be selected, in part, because of the learning value to the intended user (for example, demonstrating principles and methods that can be applied by the user to other topics) and the ability to sustain the improvements that they trigger.

• Likelihood of Success (Readiness)—Identify topics that are of interest to the relevant stakeholders who will be asked to make improvements. This criterion recognizes the fact that significant improvement is not likely to occur if some pivotal individuals (for example, chiefs of Medicine, department heads, and clinical leaders) do not welcome or are not capable of participating in the project.

Comment: Several commenters stated that the regulation should eliminate the requirement to use QIO data. Others suggested that hospitals, especially rural hospitals, should be required to only use QIO data that is relevant to its own QAPI programs.

Response: A hospital is not required to use QIO data. The QAPI program must incorporate quality indicator data that may include data, for example, QIO data or other relevant data.

Comment: Several commenters stated that the quality of care and patient outcomes should be the focus of the QAPI program, not the usage of specific data. Some commenters stated the proposed data requirement was too prescriptive and unclear. Others stated that many providers are unaware of what ''QIO data'' is, how to access it, and the associated costs, if any. Several commenters requested this provision be removed.

Response: As stated previously, there is no requirement to use QIO data. QIO data is generally relevant information submitted to (or received) from the hospital's QIO. It can be a good source of quality indicator data to inform the hospital of areas where improvements are necessary. It is important that each quality improvement project have valid and representative baseline data; however, that baseline data may be from QIO data or from another source.

Comment: A commenter stated QIO cooperative projects, rules, and policies are already established and stated referring to them in regulatory text is unnecessary.

Response: As stated before, the QIOs are making great strides in national quality projects; however, hospitals are free to work on projects of their own design as long as the effort is comparable to QIO projects. Our intent is to allow hospitals the greatest flexibility, by offering options and examples.

F. Assessment of Compliance and Enforcement

Through our survey process, we intend to assess whether hospitals have all of the components of a QAPI program in place. The SAs will expect hospitals to demonstrate, with objective data, that improvements have taken place in actual care outcomes, processes of care, patient satisfaction levels, hospital operations, or other performance indicators.

Comment: Many commenters strongly supported our proposal to require,

through the survey process, an assessment of the hospital's success in using performance measures and objective data to demonstrate improvements have occurred.

Response: We are encouraged by the comments that support the proposed survey focus for the QAPI requirements. Further, we recognize the need for appropriate training of our surveyors. We do not intend for surveyors to judge the measures used by a hospital. Instead, we will train the SAs to assess the hospital's success in its own efforts to improve its performance. The surveyors will ensure that the number of distinct successful improvement activities conducted annually are proportional to the scope and complexity of the hospital services, operations and patient acuity, and that improvement activities demonstrate sustained improvement over time.

Comment: A commenter stated JCAHO should be involved in enforcement, emphasizing the hospital's familiarity with the current JCAHO requirements regarding QAPI.

Response: We disagree. JCAHO is an accreditation organization that sets healthcare standards but it does not have the direct authority to enforce our regulatory requirements. We also note that compliance with our quality standards is assessed either through an accreditation process that we have determined meets or exceeds our requirements or through the survey and certification process conducted by SAs under contractual agreements with us. Ultimately, we are responsible for enforcing our own requirements; and therefore have the following hospital quality oversight responsibilities: (1) Being a prudent purchaser of quality hospital services; (2) establishing minimum standards to ensure the health and safety of our beneficiaries through the CoPs; (3) ensuring that hospitals are in compliance with the CoPs; and (4) promoting quality improvement in hospitals.

Comment: Many commenters expressed concern over the lack of clarity regarding the specific documentation hospitals are required to provide to surveyors to indicate compliance on surveys and the correlation of this information in determining how these regulations improve and protect the quality of care and increase patient satisfaction. Commenters also questioned the hospital's ability to deny access to information collected for quality activities, citing confidentiality and fear of disclosure.

Response: As previously stated, surveyors will not judge the various measures used by a hospital in its QAPI program. In general, a hospital should maintain materials and documentation that it deems necessary to objectively demonstrate its QAPI goals and outcomes to a surveyor. The surveyor should, at a minimum, expect a hospital to have documentation that describes the program; assessment information (data); the rationale for prioritized improvement projects; and the progress that has been achieved. The SAs and we have the legal authority to review records pertaining to the operation of the provider, including patient medical records (including, medical error reports, and peer review information), when these documents are necessary to determine whether the provider is in compliance with the statutory and regulatory requirements for Medicare and Medicaid participation. Section 1864 of the Act authorizes SAs to determine whether an entity meets hospital qualification under section 1861 of the Act. Included in these qualifications are requirements concerning patient records, hospital administration, and medical and nursing services. The surveyor must have access to the hospital and patient records as necessary to determine compliance for participation in the Medicare program. Also, the facility denial of access to our surveyors or us may prevent us from determining that facility's compliance with program requirements. Therefore, under the statute and regulations, we may need to pursue termination proceedings.

This information is protected by the provision of section 1106 of the Act, 42 CFR 401, as well as, the survey agency's responsibilities for protecting the confidentiality of documents, as set out in sections 3300–3316 and 3318 of the State Operations Manual.

G. Responsibilities of the Hospital's Governing Body

We proposed that the hospital's governing body, medical staff, and administrative officials are responsible for ensuring that the hospital-wide QAPI efforts address identified priorities in the hospital and for implementing and evaluating improvement actions.

Comment: A commenter stated that all of proposed § 482.25(b) should be deleted because it is included in the opening paragraph for the QAPI CoP.

Response: Accountability and leadership are vital to any QAPI program, and the hospital's leadership (for example, administration and governing body) must provide the foundation for its establishment. There must be an explicit organizational goal that is demonstrated by clear leadership and support. With this, the hospital and its staff would be more likely to consider the quality program as a high priority and initiative. We have expanded the proposed standard entitled ''Program Responsibilities'' and renamed it ''Executive Responsibilities'' to more appropriately reflect the scope and intent of this standard. The organization's governing body must have an ongoing commitment to creating safe systems of care. The IOM report, ''To Err is Human,'' states, ''Senior level leadership should define program objectives, plans, personnel and budget, and should monitor QAPI activities by requiring reports to the executive committee and board of directors.'' The executive responsibilities standard clarifies that it is the responsibility of the hospital's governing body to establish a culture of safety and quality and to define the importance of QAPI activities throughout the institution. The culture of a hospital plays a critical role in how well patient safety and quality of care are viewed throughout the institution. The standard also requires the governing body to ensure that the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated.

Comment: A commenter stated that the governing body should not be held accountable for the performance of independent contractors in the medical staff because the governing body lacks the scientific knowledge to judge physicians.

Response: We are not asking, nor do we expect, the governing body to ''judge'' physicians or any member of the multidisciplinary team. The governing body is responsible for assuring that there is an ongoing, effective, internal QAPI program and that this program methodically identifies and addresses priorities in the hospital and initiates efforts to evaluate and address improvement actions. The analysis of these projects and events identified by the quality initiative is an integral part of the program. It is not a separate function performed by the governing body. We expect hospitals to learn from these efforts and initiate plans and actions to improve patient care outcomes, safety, and satisfaction.

H. Autopsies

We proposed that hospitals must attempt to secure autopsies in all cases of unusual deaths and in the interest of medical, legal, and educational endeavors. The mechanism for documenting permission to perform an

autopsy must be defined. There must be a system for notifying the medical staff, specifically the attending practitioner, when performing an autopsy.

Comment: A few commenters asked why we would give hospitals (instead of the medical staff) the responsibility for securing autopsies and then notifying the medical staff and attending practitioner. These commenters suggested that this authority be maintained under the auspices of the physician. Conversely, other commenters supported this shift of authority, but strongly opposed the elimination of the medical staff CoP, stating this group is essential for quality oversight of any hospital. There were other commenters that requested that we delete the autopsy requirements and administrative assessments. These commenters believe that these requirements were particularly burdensome and may have an adverse effect on patient care or are too difficult to measure.

Response: We have removed the proposed standard for autopsies under the QAPI condition. However, we will retain the current autopsy requirements at § 482.22. This requirement states that the medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical, legal and educational interests.

I. Future Development of a Core Set of Evidenced-Based Standardized Measures for Hospitals

We have a national strategy for standardizing performance measurement and data collection that is, in part, an outgrowth of the creation of a National Forum for Health Care Quality Measurement and Reporting (National Quality Forum (NQF)). In May 1999, the NQF was organized in the private sector and brought together private and public purchasers and stakeholders to reach a consensus on standardizing a national approach to performance measurement in healthcare. The NQF adopted the concepts of our guiding principles and incorporated them into its own national strategy to standardize performance.

The three principles that guide our national performance measurement strategy are as follows:

- *Performance measures should be consumer- and purchaser-driven.* A major challenge for us is to determine value through quality measurement and to use the information to purchase better healthcare services for beneficiaries. This should be done through collaboration with other purchasers.
- *Performance measures and the collection tools needed to collect them should be in the public domain with a publicly held copyright.* This means that the public good is served through a broader access to the measures and data collection tools. Further, the government and the public need unrestricted access to the measures and measurement systems to be able to adopt, collect, revise and report results to the public.
- *The content and collection of data and performance measures derived from that data should be standardized.* Standardization leads to more useful information for consumers and purchasers and reduces the burden for providers and plans.

Our performance measurement strategy is designed to achieve our mission of: (1) Providing consumer information that assists beneficiaries in making choices in healthcare; (2) setting process and outcome criteria to which plans/providers are held accountable; and (3) facilitating quality improvement activities at the program level focusing on national Medicare and Medicaid key clinical priorities at the plan and provider level.

1. Why Standardized Measures?

Quality improvement is difficult to measure and accountability for quality improvement may be a new concept for some providers of care. A quality improvement program is developed from the collection of data within a facility that are analyzed and used internally to develop and measure the impact of standards of practice, processes, and systems. The organization learns to compare its measured performance results, using appropriate risk-adjustment techniques, with standardized benchmarks used nationally to evaluate how well it is doing compared to similar institutions across the nation. In order to develop these standardized benchmarks, we participate in pilot projects with our QIOs and accrediting bodies. We are committed to partnering with consumers, health plans, providers, purchasers, States, industry and professional representatives, and accrediting organizations over time, to identify key performance measures of quality that guide what institutions can measure internally for comparisons of standardized measures. Standardization of these measures is key to assure comparability of performance and to make these measures appropriate for accountability purposes. Further refinement and testing of select measures that are suitable for public reporting of comparisons of performance among like-providers is part of the long-range plan for the use of standardized measures. Ultimately, a continuous process of refinement and flexibility in the selection of a core set of standardized measures is our long-term goal. The requirement for hospitals to conduct ongoing monitoring and evaluation of their internal processes and systems through the QAPI program will continue to be a part of the effort for improving the quality of care provided. Standardized measurements will complement QAPI, not replace it.

2. How Will This Program Be Implemented in Hospitals?

We are engaged in multiple initiatives that address the development of a core set of evidence-based standardized performance measures, which will be universally applied to hospitals. One initiative is a pilot project where we intend to work with multiple partners, including the JCAHO and the QIOs, in the development of a core set of evidence-based standardized performance measures, which are expected to be presented to the NQF for endorsement. Additionally, we are working with other organizations, like the NQF, on an initiative that will further the national private/public effort to standardize a core set of hospital performance measures that include patient safety measures. Until a core set of measures is developed, we expect hospitals to conduct their QAPI programs using pertinent objective measures of performance. Hospitals also have the opportunity to pursue measurement of clinical practices in focus areas of national high priority. One example of this could be a hospital's assessment of physician prescribing patterns in comparison to evidence-based clinical guidelines, in an effort to reduce the prevalence of antimicrobial resistant organisms.

3. Reporting

Since the standardized measures project would involve the Federal government, as well as accrediting bodies and other organizations, its development would not only lessen the burden on hospitals but would also support our goal of developing a regulation that would be universally endorsed. In this process, we will determine how data could be collected, validated, and presented to the general public, and determine the impact of providing this type of information. In the December 19, 1997 proposed rule we stated the following:

Under this proposed rule, we would require a hospital to engage in a quality assessment and performance improvement program that uses objective measures, but we are not

proposing that a hospital be required to participate in a system of performance measurement at this time * * * however, we intend to develop such a requirement for inclusion in our final rule and welcome public comments addressing the appropriateness of such a requirement or how it could best be structured.

In this final rule, we are not setting a requirement for using and reporting on a core set of evidence-based performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will assess issues such as commonality of data elements, standardization, and reporting systems. We will inform hospitals and the public of the specifics of and the methods for reporting these performance measures via future rulemaking. This will give the public the opportunity to comment on the core measures before implementation.

4. Core Set of Standardized Performance Measures

In the December 19, 1997 preamble to the proposed QAPI Condition, we also asked for responses and comments to seven questions we posed to the public regarding the development of standardized performance measures for hospitals.

a. *Question 1:* Should CMS assume a leadership role in developing the measures?

Comment: Several commenters stated that we should assume a leadership role in developing a national database of clinical outcomes accessible to all healthcare provider organizations. We received comments from providers as well as practitioners stating that it was the Federal Government's responsibility to set quality standards for the nation with its parallel roles of protecting consumers and supporting healthcare professionals.

Response: We remain committed to our leadership role of protecting consumers and supporting healthcare professionals. We are exploring the concept of requiring Medicare- and Medicaid-participating hospitals to report on a standardized set of performance measures that can be used nationwide. Currently, we are negotiating the terms of a pilot project. The pilot project will be conducted through a collaborative effort among several States, accrediting bodies, and QIOs. These organizations will evaluate a set of standardized performance measures that can be used nationwide. We believe the outcome of this project will yield valuable information regarding the efficacy of data, as well as the effectiveness of requiring Medicare- and Medicaid-participating hospitals to report on a standardized set of performance measures that can be used for national comparative studies.

Comment: Many commenters stated our role should be limited to convening a group of experts and stakeholders to develop performance measures, while others argued that we should not be involved in this process or limit its role to nonaccredited hospitals. Some commenters believed that we should not enter into public/private partnerships to develop measures, stating high accreditation costs would be passed on to consumers. While others stated an outcome measure database should be developed with input from CMS regional office and State agency staff.

Response: We have established a performance measurement leadership agenda to pursue standardization of hospital performance measurement. We plan to work with organizations like the NQF, hospital associations, and accrediting organizations to standardize a core set of hospital performance measures. Through the QIO Program 6th Scope of Work, we currently have performance measures for pneumonia, heart failure, stroke, acute myocardial infarction, diabetes, and breast cancer to offer as a starting point. As stated earlier, we are exploring conducting a pilot program to test these and other standardized measures. One goal of the QIO program is to improve the quality of care to Medicare and Medicaid beneficiaries, which is parallel with our oversight responsibilities.

Before proposing new provider requirements, we routinely network with healthcare providers, regional and State agency staff, and other interested stakeholders so that what is proposed reflects optimal provider practices, to yield optimal results. Finally, although the majority of commenters favored a standardized approach, opinions varied with respect to whom should take the leadership role in the development of these standards.

Comment: Many commenters disagreed with our goal of creating standardized performance measures. These commenters stated this approach should not be required and strongly felt that a national quality assessment database should not be established because comparisons between hospitals will not be meaningful or reliable. Additionally, other commenters expressed concern that there is no basis for recommending one indicator over another, and that reliable and valid measures do not currently exist. It was further argued, that the infrastructure and data elements for performance standards are not available, stating that clear data definitions are needed before a core data set may be implemented to increase the hospital's understanding of what is being measured and how it is being measured.

Response: As we stated previously, we believe that standardization of these measures is key to assuring comparability of performance and to making these measures appropriate for accountability purposes. Further refinement and testing of select measures that are suitable for public reporting of comparisons of performance among like-providers is part of our long-range plan. Ultimately, a continuous process of refinement and flexibility in the selection of a core set of standardized measures will benefit both hospitals and beneficiaries as individual hospital performance on standardized measures will invoke appropriate improvement activities to improve overall patient care.

b. *Question 2:* How should CMS proceed to develop and implement the measures?

Comment: Several commenters stated that QIOs should formalize a national database.

Response: We plan to utilize all available resources, including QIOs and organizations like the NQF, to formalize and finalize a source for comparable data to be used nationwide. We currently have some data entry software systems that we offer to providers. The systems have tutorial help for users to gain an overall understanding of the applications, with emphasis on designing data entry systems, explaining how to create an analysis, and evaluating the quality of the abstracted data.

Comment: Some commenters were concerned with the impact that the requirements would have on rural hospitals and suggested that we defer to JCAHO's ORYX. The commenters believe that ORYX recognizes these needs.

Response: We do not agree with deferring to the JCAHO to establish a set of standardized performance measures for Medicare- and Medicaid-participating hospitals. However, we recognize the JCAHO's efforts with regard to performance measures and we acknowledge the need to collaborate with accrediting bodies to facilitate the most appropriate principles for standardizing performance measures. While we are aware that there is no single system available for the measurement of a hospital's performance, we are also aware of efforts by the hospital industry to find ways to increase the use of the systems

that are currently available. In response to the unique needs of rural hospitals, we want to assure these hospitals that our goal for the utilization of performance measures considers the hospital's size and available resources. We will take into account the special circumstances faced by rural hospitals and ensure their needs are considered when developing performance standards in the future.

Meaningful performance programs are often derived from simple designs that use direct and uncomplicated measures. One of the factors that has impeded this progress is the lack of standardization where possible. These comments reinforce the importance of our adoption of a national performance measurement strategy.

Comment: Commenters stated that we should defer to the private sector until the field of clinical outcome measures has matured, stating there is a lack of consensus in this area. Commenters suggested that we clarify our intent by addressing such issues as data element definition, risk-adjustment methodologies, audit criteria, and modification of existing commercial monitoring systems before mandating a Federal requirement.

Response: We agree that these issues must be addressed before proceeding to mandate utilization of a core set of performance measures. We plan to work with all of our partners, stakeholders, and other interested parties in developing these outcome measures and believe this will provide scientific evidence needed for our national performance measurement strategy.

Comment: A commenter stated we must develop an outcomes survey process independent of JCAHO, noting current significant inconsistencies between JCAHO and State survey agency findings.

Response: We intend, through our survey process, to assess the hospital's success in using performance measures principally in terms of whether the hospital can demonstrate with objective data that sustained improvements have taken place. We recognize the need for surveyor training and education in the area of quality improvement. We do not intend and would not be in a position to judge the measures ourselves. Instead, we would assess the hospital's use of these measures to improve its performance. Whenever the state agency surveyors enter the hospital to conduct a survey they will evaluate the hospital's program and its own internal evaluation process. When there is an onsite review of the hospital's QAPI program, the surveyors determine whether or not the hospital is meeting the QAPI CoP requirements. Following the existing survey process and procedures, if the SA determines that the hospital is significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs. The hospital is then given the opportunity to submit a plan of correction. The SA would conduct a follow-up survey to assess whether the hospital is now in compliance with all of the requirements, prior to the actual termination taking place.

Regarding the survey process, our survey process is developed independent of JCAHO's. In addition, we have an ongoing effort with JCAHO to address inconsistency in survey findings.

c. *Question 3:* If CMS does assume a leadership role in this area and hospitals invest in the development of multiple systems, would the overall burden be greater than if a single system had been imposed at the outset?

Comment: The majority of commenters focused on the burden that this requirement would impose on hospitals and the healthcare industry. These commenters argued that the increased burden is due to the lack of standardization among technology companies and programs, not due to lack of interest and willingness of providers. These commenters offered the suggestion that we develop and require a single set of performance measures, but allow hospitals to develop their own system as long as it meets established criteria. In like spirit, commenters suggested requiring companies that develop approved systems to include specific attributes of the prescribed measurement system that will be evaluated. The overall tone of the comments genuinely stressed the need for adequate time for any system implementation once decided. Commenters also requested an exemption for rural hospitals stating the needs of these facilities are unique and would not be best served by such a standardized system.

Response: We will consider all possibilities that will reduce burden and enhance a hospital's ability to successfully transition to a single system. We continue to consider the geographical and financial needs of individual hospitals, but we strive to offer the same basic protections and safeguards to all patients regardless of the hospital in which they receive services.

Comment: A commenter stated that we should use available resources, such as Medicare-contracted utilization and quality assurance organizations, QIOs, and other resources. This commenter requested that we outline the current resources that are available to hospitals via these organizations.

Response: It is our intention to avail ourselves of quality assessment resources. We have considered integrating standardized measurement data sets into a system that could provide access, by an institution, to data reported to a QIO.

d. *Question 4:* If CMS does not assume a leadership role in this area and individual hospitals adopt multiple systems that produce nonstandardized data, to what extent would it be difficult to make comparisons between hospitals?

Comment: Several commenters strongly disagreed with our proposal to allow multiple systems to be used in making comparisons between hospitals. They believe that inherent differences in systems and lack of uniformity provide too many variables to accurately compare hospitals.

Response: We understand the commenters' concerns. Many hospitals will need more experience with data collection methods and in the design, implementation, and monitoring of improvement projects. We realize the difficulty in assessing comparability of hospital performance without the requirement of hospitals to utilize like systems. As stated in the December 19, 1997 preamble of the proposed rule, we sought comment on establishing evaluation criteria that must be a part of the system or systems the hospital may choose.

Currently, hospitals across the country use a wide variety of measurement systems and performance indicators to assess the quality of care delivered. The number of these performance measures has increased in recent years. Hospitals are committing substantial and increasing resources for data collection and measurement, as both consumers and purchasers demand greater accountability from their healthcare providers. Since the various measures are not standardized, the data cannot be used to make accurate comparisons about the quality of care among hospitals.

In December 2002, the American Hospital Association (AHA), the Federation of American Hospitals (FAH), and the Association of American Medical Colleges launched a national voluntary initiative to collect and report hospital quality performance information. This effort is intended to make critical information about hospital performance accessible to the pubic and to inform and invigorate efforts to

improve quality. Voluntary reporting is an essential first step to realize this goal. An important component of this coordinated effort is the identification and development of tools for standardizing data collection and making these tools readily available to the industry. We have tools available for utilization that are refined as needed, to include relevant data elements that capture the information needed or the clinical area under assessment. For example, data elements used for collecting information about a patient's experience with acute myocardial infarction would include portions that differ from data elements needed to collect information about a patient's experience with pneumonia. We recognize that not only are the tools important, but even more important are clear definitions to allow consistent categorization and counting of events or values for measurement. Future priorities and measures will be informed by a forthcoming report from the IOM that will identify 15 to 20 priority areas for quality improvement. Measures will be drawn from those endorsed by NQF; measures will be sought that respond to the six aims set forth in IOM's ''Crossing the Quality Chasm,'' and where possible will include cross-cutting measures. The entire spectrum of stakeholders will be engaged to work toward focusing national public reporting of hospital performance on agreed-upon priorities and NQF-endorsed measures.

Comment: Some commenters stated that JCAHO and NCQA have standardized indicator systems; and therefore, we should not proceed unless it can consolidate and remove existing systems. Numerous commenters stated that the burden should not be placed on the hospitals to invest resources in the development of individual hospital systems, in lieu of the increased resources needed for the collection and analysis of outcome data.

Response: We are aware that there may be costs assumed by hospitals in choosing different systems. The methods and processes for collection of data vary widely. Our interest lies within the ability of hospitals to be measured against one another when different systems are used. We did not specifically propose that hospitals be required to participate with other hospitals in a system of performance measurement. Although we stated this was our intention for inclusion in the final rule, standardized outcome measures that can be used nationwide have not been established; therefore, we have not set forth this requirement in the final rule. Regarding the existence of proprietary indicator systems, we have no authority to ''remove'' these systems.

e. *Question 5:* Should CMS require or encourage hospitals to use standardized measures that some accredited hospitals are using?

Comment: Some commenters supported using standardized measures used by accredited hospitals. In contrast, many commenters believed that the measures used by accredited hospitals are outdated.

Response: We intend to require that hospitals use standardized measures. We are committed to advancing the scientific effort already underway nationally to standardize the specifications of measures (that is, the data dictionaries and other elements that define quality indicators). We are working in partnership with the QIO program, State initiatives, the NQF or similar organizations, and accrediting bodies in national efforts being conducted to identify and develop standardized specifications. These specifications would then be presented to the NQF or similar organizations for endorsement and subsequently published in future rulemaking. Our position is that any system of measures that incorporates these specifications would be acceptable for use by hospitals. Our concern focuses on how a measure of quality can be standardized for longitudinal comparative purposes among similar hospitals and includes public reporting. Purchasers and consumers benefit from the establishment of measures that could be used to publicly report hospital-specific performance across the full spectrum of hospitals in the United States. Hospitals benefit from a reduction in burden in data collection and measurement, and an ability to obtain comparative data to evaluate and improve their performance. A collaborative effort to develop standardized measures will provide the basis for an initial measurement set for assessment and reporting of hospital performance. Having purchasers and consumers provide the leadership in defining key content areas for the first set of measures and obtaining consensus around these validated measures as a standardized reporting set would be a major achievement in improving the quality of care in the nation. For example, standardized measures of medical errors could be used widely as part of a hospital's medical error reduction program and ultimately for accountability. We believe that requiring standardized data collection and reporting on consensus-developed, scientifically based measures, is an opportunity for hospitals, purchaser and consumers to work jointly to improve the quality of hospital care. The precise measures to be required will be determined by the Secretary and communicated to the public for comment before they are initiated.

Comment: Some commenters stated that the area of performance improvement needs further development before we require specific measures.

Response: We agree that there is not a wide menu of available performance measures that have proven to be reliable and valid that could be offered to a hospital to use. Currently, we have not set forth requirements; therefore, hospitals will be able to evaluate themselves on their own data.

f. *Question 6:* Would it be appropriate for CMS to include ''placeholder'' language in the revised CoPs concerning the eventual need for hospitals to report relevant data, or is this premature?

Comment: The majority of commenters agreed with our plan and supported the goals and objectives of a core set of standardized measures. Some commenters believed that these measures should not replace organization-specific projects. They stated that the technical issues surrounding data definitions, uniform systems, and burden, specifically regarding the ability of hospitals to utilize existing information systems, would have to be addressed.

Response: In the preamble of the proposed rule, we solicited public comment on standards regarding the development and implementation of a standardized set of performance measures to be used nationwide. At that time, we did not propose a requirement for hospitals to participate in a system of performance measurement with other hospitals but we stated that we intend to in the future. We recognize the specific issues that need to be addressed (for example, technical issues surrounding data definitions, uniform systems, and costs) before implementation of a set of standardized performance measures that can be used nationwide. Hopefully, these measures will help hospitals to identify organizational-specific projects.

Comment: Many commenters supported our approach to include placeholder language, because commenters believe it will take a minimum of 2 years for us to develop standardized measures. Some commenters stated placeholder language is premature pending extensive research to insure the accuracy of standardized data, concluding that the QAPI condition be modified at a later date as necessary. Others felt this unnecessary

due to the requirement for accrediting bodies to report data.

Response: We remain committed to developing a core set of standardized performance measures but we have decided not to include ''placeholder'' language in this final rule. A core set of standardized performance measures, as well as the method of reporting these measures, will be defined in a future rulemaking document.

g. *Question 7:* If CMS should include ''placeholder'' language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

Comment: Several commenters wanted to know our projected timeframes for implementation. Others requested that we clarify whether standardized reporting and performance measures will be based solely on standardized clinical data and not on individual programs or projects at the hospital level.

Response: We realize that hospitals will need more experience with data collection methods for standardized measurement. Implementation timeframes for the standardized performance measures and the data to be reported will be presented to the public for comment in a separate rulemaking document.

Comment: Many commenters stated that the primary purpose for establishing a core set of measures is not quality improvement, but rather public accountability and data comparison. These commenters stated that meaningful improvement is best achieved by allowing caregivers the flexibility to identify opportunities for improvement. Commenters added that our focus should be on the hospital's mission and patient quality of care needs.

Response: We agree that a major reason for reporting on standardized data and core measures is public accountability and data comparison. However, we do not believe this QAPI regulation prohibits the hospital from exploring its own methods and implementing actions that are specific to its institution. Furthermore, we are committed to increasing consumer and patient awareness and facilitating the use of healthcare quality information in making key healthcare decisions.

Comment: A commenter suggested that we develop a preliminary set of measures from data on adverse patient events while a complete set of measures is being developed.

Response: After the release of the IOM report, ''To Err is Human,'' as well as the response by the QuIC, the NQF was given the task of identifying a list of adverse events that should never occur, however, the task has not been completed. We expect, as a part of the hospital's error reduction program, that each hospital will assess institutional adverse events and incorporate this information into its QAPI. For example, if the hospital has had patients that experience adverse reactions, serious harm, or death due to the incorrect administration of intravenous potassium, the hospital should perform an analysis of these events to determine the process that allowed these mistakes and initiate a plan to correct the problem.

Comment: Several commenters stated that we should defer to JCAHO and not create a separate system of performance measures for hospitals, stating the proposed requirement is not consistent with JCAHO's agenda for change.

Response: Although we value JCAHO's role in hospital oversight and quality improvement initiatives, we have responsibility and accountability for quality of care in Medicare- and Medicaid-participating hospitals. We believe that we must directly establish a system of performance measurement for hospitals and maintain a leadership role in hospital oversight. In addition, we are aware of JCAHO's agenda for change. Our representatives sit on key measurement committees and on the various JCAHO clinical advisory panels charged with selection of the initial set of measures. CMS and JCAHO will strive to minimize burden on hospitals through the selection of a single set of core measures. Finally, we are incorporating criteria that will create a minimum amount of burden on hospitals, especially those hospitals that are subject to more than one method of surveillance.

5. Nonaccredited Hospital Participation in Performance Measurement

We also invited comment on whether we should require nonaccredited hospitals to participate in one or more performance measurement systems as part of their overall QAPI program (both internally and externally). We received a number of comments on this provision.

Comment: Many commenters supported the requirement that these hospitals participate in a facility-specific or internal QAPI program. They also stated that for external participation (that is, comparison against national benchmarks) it is premature to propose a specific set of quality indicators or performance measures for nonaccredited hospitals.

Response: We do not expect the same utilization of performance measures for small hospitals as we would for large hospitals. We recognize that collection and analysis of clinical outcome data may represent an increased burden on some hospitals, particularly on the nonaccredited hospitals that are routinely subject to our survey process. These nonaccredited hospitals typically are smaller than accredited hospitals, located in more sparsely populated areas, and may not have the resources for extensive data gathering and reporting. Given the uncertain readiness of some individual hospitals to comply with performance expectations under this final rule, quantitative analysis of the effects of these proposed changes is not possible. Hospitals with QAPI programs already in place that meet these requirements, at a minimum level if not in whole, may see little increased burden. However, nonaccredited hospitals are still required to follow this CoP as participants in the Medicare and Medicaid programs. Rather than mandating specific areas of assessment and data collection, this final rule gives hospitals flexibility to identify their own measures of performance for the activities they identify as priorities.

Comment: Some commenters offered suggestions that hospitals be allowed the option of using measures developed by QIOs because these measures will have wider application.

Response: Although hospitals are not required to participate with QIOs on their projects, we recommend that the QIO be used as a resource. By working with its QIO, a hospital will reap the benefits of a more standardized, streamlined, and cost-effective approach to quality improvement.

J. Reporting

As stated earlier, since the standardized measures project would involve the Federal government, as well as accrediting bodies and other organizations like the NQF, its development would not only lessen the burden on hospitals but would also support our goal of developing a regulation that would be universally endorsed by all. In that process, we would determine how data can be collected, validated, and presented to the general public, and determine the impact of providing this type of information. In the proposed rule, we considered requiring hospitals to report certain data elements (for example, patient falls, injuries, and medication errors) to us to serve as the basis of a performance database, which could then be used for provider improvement, consumer information, and other

purposes; however, sufficient work in this area has not been performed. Therefore, we have not included a requirement for hospitals to report certain data elements in this final rule. As standardized measures are developed and implemented, they will complement, not replace the QAPI process.

Comment: Commenters cited the importance of the provision requiring hospitals to share collected information with patients and consumers, and supported information sharing to facilitate decisions based on quality. Many of these commenters felt as though it was not only prudent, but the Federal government's responsibility to ensure the availability of this information.

Response: We agree. We have the responsibility to increase awareness of patient safety issues and the role beneficiaries can play in enhancing patient safety in general. We would like to enable patients and family members to become more involved in their care and to be active participants in the decision-making that impacts their care. We support the development of patient safety messages and themes that can be used by healthcare purchasers, and consumers to guide their choices in the selection of quality healthcare.

V. Provisions of the Final Rule

Since this final rule sets forth the requirements for the QAPI CoP only, we are placing the QAPI CoP with the existing hospital CoPs under Subpart C—Basic Hospital Functions at § 482.21 that will replace the existing Quality Assurance requirements. The five standards in this CoP will set forth the requirements for the development of an effective ongoing hospital-wide QAPI program that will focus on indicators related to improve health outcomes and prevention, and reduction of medical errors. As with the existing CoPs, the enforceability of the CoPs will be rooted in the evidence found during the onsite survey. The requirements of the QAPI CoP are as follows:

Section 482.21

This condition requires that hospitals must develop, implement, maintain, and evaluate their own QAPI programs. We have retained the provision requiring the hospital's QAPI program to reflect the complexity of the hospital's services and operations. We state that the QAPI program must be hospital-wide, ongoing and focus on indicators related to improved health outcomes. We also added language to—(1) stress the importance of the inclusion of measures that foster the prevention and reduction of medical errors; and (2) require hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS.

Section 482.21(a)

The first standard, Program Scope, requires that a hospital's QAPI program include an ongoing program that shows measurable improvements in indicators for which there is evidence that they will improve health outcomes, and identify and reduce medical errors. There is also a provision that the hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations. We have deleted the proposed requirement for the mandated assessment of 12 minimum areas.

Section 482.21(b)

The second standard, Program Data, provides the framework and clearly defines the expectations for hospitals regarding data the hospital must use as part of its QAPI program. It contains the provisions presented in the proposed rule, that described the type of data to be used including patient care and other data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

Section 482.21(c)

The third standard, Program Activities, has been added to clarify the hospital's responsibilities. This section contains a requirement on setting priorities for performance improvement, previously found in the proposed rule at § 482.25(a)(5), with some modifications based on comments. The first requirement under the program activities standard requires hospitals to set priorities for improvement, considering prevalence and severity or incidence, or both, of high-risk, high volume or problem prone areas, and giving priority to improvement activities that affect health outcomes, patient safety, and quality of care. A hospital's performance improvement activities should track adverse patient events, analyze their causes, and implement preventive actions and mechanisms of feedback and learning throughout the hospital. This must include incidents of medical errors and adverse patient events. Finally, hospitals are required to take actions that result in performance improvements. After implementing actions, the hospital must measure its success and track its performance to assure that improvements are sustained.

Section 482.21(d)

The fourth standard, Performance Improvement Projects, has been added to distinguish the requirements for improvement projects from program activities as requested by the commenters. We require that the number of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. Demonstration of minimum effort will be achieved by requiring hospitals to document what projects they are conducting, the reason for conducting these projects, and measurable progress achieved. The standard does not require hospitals to participate in a QIO cooperative project but its own projects are required to be of comparable effort.

Section 482.21(e)

The fifth standard, Executive Responsibilities, clarifies our intent to hold the hospital's leadership responsible and accountable for QAPI activities. We have maintained the requirement ensuring that a hospital-wide QAPI program addresses priorities and implements, maintains, and evaluates all improvement actions. This standard is further strengthened by requiring the hospital's governing body to provide strong, clear, and visible attention to setting expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients.

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 effects, distributive impacts, and equity.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless we certify that a final rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. We consider most hospitals small entities, either by nonprofit status or by

having revenues between $6 million and $29 million. Individuals and States are not considered small entities. We certify that this final rule will not have a significant impact on small entities.

Also, 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. That analysis must conform to the revision 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. We certify that this final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandate Reform Act of 1995 also requires that agencies assess anticipated costs and benefits for any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule has no mandated effect on State, local, tribal governments, or on the private sector that reach the threshold of section 202.

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 compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In 1994, we invited all interested parties to a town hall meeting to discuss our plans to set forth regulations to establish a new approach to improving the quality of healthcare provided in hospitals. Parties from the Association of Health Facility Survey Agencies, hospital associations, and other stakeholders were in attendance. These agencies were given the opportunity to provide input and were generally in favor of our plans.

We welcomed comments on our December 1997 proposed rule. We received a number of comments on our QAPI CoP but we did not receive any comments indicating that States would be adversely affected by this rulemaking.

Thus, we have examined this final rule and have determined that this final rule will not have a negative impact on the rights, rules and responsibilities of State, local or tribal governments.

B. Anticipated Effects

In December 1997, we proposed to revise all of the hospital CoPs that emphasized lessening Federal regulations to eliminate unnecessary structural and process requirements, to focus on outcomes of care, to allow greater flexibility to hospitals and practitioners to meet quality standards, and to place a stronger emphasis on QAPI.

Within this newly revised CoP we proposed to establish a QAPI program that encompasses all hospital services and operations. We solicited comments on the QAPI provisions and received overwhelming support for its establishment. There was consensus among, provider, public, professional organizations, accrediting organizations, and the Congress that supported its establishment. The need again arose for a program due to serious concern regarding patient safety and medical errors after publication of the 1999 IOM's report along with the response to the report. These factors led us to set forth this final rule to ensure high quality of care in a safe environment in our nation's hospitals.

1. Effect on Hospitals

Given the shift to regulatory flexibility, for the most part, we are not prescribing the exact process hospitals must follow to meet the regulatory requirements of the QAPI CoP. However, the following components must be established and maintained in the development of a QAPI program: hospitals will be required to have a QAPI program encompassing all services and operations that focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

Some hospitals may need to revise their existing programs to conform to this regulation; however, we do not believe this CoP will impose a significant economic burden above what hospitals are already doing to meet the current quality assurance CoP.

Currently under § 482.21, hospitals must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provisions of patient care. Under the existing requirement hospitals must have a written plan of implementation, this plan must include all organized services and contractors. The hospital is also required to document appropriate remedial actions to address deficiencies found through the quality assurance program, as well as the outcome of the remedial actions. However, as a hospital's QAPI program matures, we expect that hospitals will be engaging in quality improvement activities in an expanding number of areas as resources are redirected from areas of program success to new areas, but existing improvements are sustained.

This QAPI CoP focuses provider efforts on the actual care delivered to the patient, the performance of the hospital as an organization, and the impact of the treatment furnished by the hospital on the health status of its patients. In developing this CoP, we have included structure and process-oriented requirements only where we believe they are essential to achieving desired patient outcomes or preventing harmful outcomes. This approach is intended to incorporate into our regulations current best practices in well-managed hospitals, relying on each hospital to identify and resolve its performance problems in the most effective and efficient manner possible.

This QAPI CoP is in fact an extension and modification of the existing quality assurance CoP found at § 482.21. We anticipate that hospitals, both large and small, rural and urban, will or already use a variety of data to inform their internal QAPI programs. Some of these data may be measures designed by the hospital itself, while others will be developed through research or by consensus groups or other sources outside the hospital. Thus, the impact will vary according to each hospitals current quality improvement activities and programs. The impact will also vary and is subject in large part to their decision-making, current policies and procedures, and level of compliance with existing quality assurance regulations. It is important to note that due to the flexibility of these provisions, the extent of the economic impact of most of these requirements is dependent upon decisions made by the hospital. We believe that this CoP will minimize the administrative burden on hospital's to comply with detailed Federal requirements. Instead, this QAPI CoP will provide hospitals with more flexibility to determine how best to pursue our shared quality of care objectives in the most cost-effective manner.

We expect hospitals to develop different approaches to compliance based on their varying resources, patient populations and other factors. There are several provisions that will impact the hospital's processes to a greater or lesser degree. Specifically, this CoP does introduce a new concept that the hospital will have to develop an internal error prevention and reduction program to ensure optimum outcomes for its patients.

The requirements of the rule effect current industry practice. Therefore, hospitals with QAPI programs already in place that meet these requirements, at a minimum level if not in whole, may see little increased burden. Hospitals

that do not meet the current QA CoP, may encounter an increased burden in the short-term because resources would have to be devoted to the development of a QAPI program that covers the complexity and scope of the particular hospital's services. Based upon information that we do possess, small and rural hospitals may be the least prepared and may experience an increased burden in implementation of a QAPI program. However, even in the situations where the proposed requirements could result in some immediate costs to an individual hospital (that is, the development and utilization of performance measures to be used in their QAPI program), we believe the changes the hospital would make would produce real but difficult to estimate long-term economic benefits to the hospital, such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the hospital. Additionally, as hospitals are encouraged to choose projects that reflect the scope of their services, it will become increasingly difficult to quantify the burden of data collection. As QAPI projects vary within each hospital and amongst all hospitals, so will the quantity of and the time required for data collection. Overall, we believe that the benefits of complying with the QAPI CoP will outweigh any associated burden.

For the sake of quantitative analysis, we have based our figures on all hospitals having to develop or update their QAPI program. The projected training time for staff is expected to cost an average hospital allocating a group of 10 clinicians with various duties and responsibilities, approximately $840 based on a average hourly rate of $28 per hour (3 hours x $28 per hour x 10 clinicians = $840). We have proposed 12 hours of training for the QAPI coordinator, which is projected to cost $360, based on a average salary of $30 per hour (12 hours x $30 per hour x 1 coordinator). The total hourly burden for each hospital is projected to be 42 hours (3 hours x 10 staff) and (12 hours x 1 coordinator).

Hours/ Estimated salary/Number of hospitals	Annual burden hours	Annual cost estimate
10 clinicians × 6,069 hospitals × 3 hours × $28 per hour	182,070	$5,097,960
1 coordinator × 6,069 hospitals × 12 hours × $30 per hour	72,828	2,184,840
Subtotal	254,898	7.3 million

We estimate that the burden associated with updating and in some instances, writing the internal policies would be an average of 8 hours annually. If the updating or writing of the internal policies is done by the nurse coordinator, we estimate the cost at $240 a year (8 hours X 30 per hour). However, we believe that this figure may be much lower, since many hospitals have existing internal quality improvement programs.

Hours/ Estimated salary/ Number of hospitals	Annual cost estimate
1 coordinator × $30 per hour × 8 hours × 6,069 hospitals	$1,456,560

We also note that the following factors may also affect the costs of updating and writing of the internal policies:

• *Additional Staff Costs.* Examples of these costs include— (1) physician or other professional staff reviewing the internal policies; and (2) clerical staff providing typing, printing, or copying support.

• *Staff Training Costs.* Staff may need additional training to write, update or review the hospital's internal policies.

• *Printing and Copying Costs.* These costs are dependent upon the magnitude of the hospital's changes to its internal policies and the number of copies of the policy that are made available to staff.

Policy development is necessary to patient health and safety because the by-laws provide the framework within which all patient care services are furnished. The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under Medicare and Medicaid.

Requirement	Number of hospitals	Annual hours per hospital	Annual burden hours
Policy Development	6,069	8	48,552

Hours/Estimated salary/Number of hospitals	Annual burden hours	Annual cost estimate
2.5 hours × 2 hospitals	5	
5 physicians × .40 hours each × $65 per hour × 2 hospitals		$260.00
1 clerical × .50 hours × $6 per hour × 2 hospitals		6.00
Subtotals	5	266.00

2. Effect on Beneficiaries

The Federal Government plays many important roles that affect the quality of healthcare Americans receive. In fact, the Federal Government is the largest purchaser and provider of healthcare services in the United States. Our goal is to improve the care delivered by providers and purchased on behalf of Federal beneficiaries, and to facilitate hospitals in developing the infrastructure needed to improve their hospital services. The implementation of the QAPI CoP will benefit and protect not only Medicare and Medicaid beneficiaries, but all patients receiving care in any of the approximately 6,100 Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. We believe the patient will benefit from the hospital establishing a QAPI program, making quality of care and patient safety

priorities. We also believe the implementation of the QAPI CoP will lead to an increase in quality care, optimal patient outcomes and a reduction in the number of medical errors.

3. Effect on the Medicare and Medicaid Programs

We do not expect the implementation of the new QAPI CoP to generate any significant cost to the Medicare or Medicaid programs. As our budget pays for survey and certification activities by the States and States already survey hospitals for compliance with the existing hospital quality assurance CoP, surveyors will only change their focus when surveying from a quality assurance approach to a QAPI approach. Surveyors will be trained on the QAPI approach during their normally scheduled training on the hospital CoPs. Therefore, we believe that there will be no additional costs associated with this training. However, as the QAPI program progresses in individual hospitals, surveyors may have to spend more time evaluating an increasingly robust quality program. These efforts are difficult to quantify.

C. Alternatives Considered

We considered adding requirements that were more prescriptive in nature. However, in response to public comments, and in recognition that this requirement will apply to hospitals of varying size, operating in wide ranges of localities, serving diverse populations, we opted not to utilize this approach. Development of more detailed strategies and policies to comply with the requirement will be left to the discretion of each hospital.

We originally proposed that hospitals use 12 minimum performance areas as the foundation for the QAPI program. However, after analysis of public comments and literature, we agreed with commenters that specifying 12 minimum areas for analysis as part of a hospital's QAPI program was too prescriptive. These commenters argued it would be more effective to allow hospitals to assess, measure, and analyze themselves, but concurred with the identification of hospital processes and functions that could produce valuable information. Alternatives were given, such as, the adaptation of JCAHO's standards, or by us merely providing the components of the QAPI program and giving the hospital the flexibility to create a program of its own design. Some commenters suggested that nonaccredited hospital be exempt from QAPI requirements until we provide scientific evidence that participation in such programs improves patient care.

Based on public comments, we have deleted the proposed requirement for hospitals to assess their performance in 12 specific areas. We agree that hospitals should be able to pursue quality improvement in a manner of their choosing. Regarding the exemption of nonaccreditied hospitals, we cannot relinquish our responsibility for assuring quality healthcare for all patients. We believe that we have provided hospitals with enough flexibility and have identified enough resources for improving the process of patient care to facilitate the development of an effective QAPI program by a hospital of any size. Therefore, we do not believe there is a need to differentiate our expectations for accredited and nonaccredited hospitals.

In the proposed rule, we also solicited comment on standards regarding the development and implementation of a set of evidence-based standardized performance measures. At that time, we did not propose a requirement for hospitals to participate in a system of performance measurements with other hospitals, but we stated that we intend to do so in the future. Many commenters supported our approach to include placeholder language, because commenters believe it will take a minimum of 2 years for us to develop standardized measures. Some commenters stated placeholder language is premature pending extensive research to insure the accuracy of standardized data, concluding that the QAPI condition be modified at a later date as necessary. In this final rule, we have considered public comments and are not setting a requirement for using and reporting on a core set of performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will inform hospitals and the public of the specifics of and the methods for reporting these performance measures for future rulemaking. This will give the public the opportunity to comment on the core measures before implementation.

Our goal is to foster and stimulate a culture of shared learning that will help to identify processes, systems, and even events that potentially or actually lead to error or poor quality care and less than optimal patient outcomes. We believe that this final rule will enable hospitals to identify and resolve performance problems specific to their situations in the most effective and efficient manner possible.

Although we view the anticipated results of this regulation as beneficial to the Medicare and Medicaid programs, as well as to Medicare beneficiaries and Medicaid recipients and State governments, it is impossible to quantify meaningfully a projection of the future effects of this standard in the event of noncompliance issues.

We believe that the foregoing analysis concludes that this regulation would not have any significant impact on the aforementioned providers. Also, the burden associated with this requirement will vary, in some instances be greater, depending on the sophistication of the hospital current QA program.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved, section 43506(c)(2)(a) of the Paperwork Reduction Action of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information collection burden; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

The title and description of the individual information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate, is the time for searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the QAPI process, including education and feedback.

Section 482.21 Condition of Participation: Quality Assessment and Performance Improvement

This revised section requires the hospital to develop, implement, and maintain an ongoing effective hospital-wide, data driven, QAPI program. The current requirements provided for the operation of an internal quality assurance program to evaluate the provision of patient care. The revised condition further requires hospitals to examine its methods and practices of providing care, identify opportunities to improve its performance, and then take actions that result in higher quality of care and improved safety for hospital patients. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the hospital, as it is free to develop a creative program that meets the needs of the hospital and reflects the scope of its services. We believe that developing the data systems necessary to implement a QAPI program and internal policies governing the hospitals approach to the development, implementation, maintenance, and evaluation of the QAPI program will impose minimal burden, depending somewhat on the level of compliance with the existing quality assurance requirements. Flexibility is provided to the hospitals to ensure that each program reflects the scope of its services and operations. We believe this requirement provides a performance expectation of hospital's setting their own goals and using information to continuously strive to improve their performance over time. Given the variability across the hospitals in size and experience and the flexibility provided by the regulation, we believe the burden associated with these requirements governing the approach to the development, implementation, and evaluation of the QAPI program will reflect that diversity. We want to provide flexibility and do not want to be prescriptive in defining hourly parameters; however, we need to quantify the burden § 482.21 associated with this requirement.

We estimate that the burden associated with updating and in some instances, developing a QAPI program would be an average of 80 hours annually (although this figure may be much lower, since many hospitals have existing internal quality improvement programs).

Requirement	Number of hospitals	Annual hours per hospital	Annual burden hours
QAPI Program Development	6,069	80	485,520

Section 482.21(b) Standard: Program Data

This regulation would require data collection and necessitates staff training on data collection. Again, we estimate the burden associated with this requirement would vary, depending on the sophistication of the hospital's quality assurance programs currently in place.

Requirement	Number of personnel per hospital	Annual hours	Number of hospitals	Annual burden
Training	10 clinicians	3 hours	6,069	182,070
	1 coordinator	12 hours	6,069	72,828
Data Collection and Analysis		80 hours	6,069	485,520
Subtotal				740,418

Section 482.21(c) Standard: Program Activities

The current QA CoP requires hospitals to document appropriate remedial actions, and address deficiencies found through its QA program. The new QAPI CoP replaces the existing QA CoP by focusing on the continuous improvement of the hospital as an organization requiring hospitals to track incidents, analyze their causes, and share and implement preventive actions and mechanisms of feedback and learning throughout the facility. We realize it is neither practical nor economically feasible to collect data and analyze all areas, processes, and systems of the hospital. Therefore, we are requiring the hospital's governing body to ensure the priorities set by the QAPI program are reflective of the hospitals services, ensure quality of care, and protect the safety of the patients. The burden associated with these requirements are captured above in sections 482.21 (a) and (b).

Section 482.21(d) Standard: Performance Improvement Projects

This new requirement reflects an interdisciplinary, coordinated approach to performance improvement. The proposed new performance improvement projects requirement sets forth the requirement that each hospital must establish a mechanism that further explores the specific needs identified in the organization's assessment. This mechanism of action is a performance improvement project. These projects demonstrate the hospital's ability to: identify problems; evaluate and track quality indicators, or other aspects of performance; and implement actions or adopt changes that reflect processes of care and hospital operations. The hospital must be able to document and demonstrate to the SA what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

We believe, that in order to comply with this QA CoP, hospitals, for the most part, are already documenting their efforts as remedial actions. Nevertheless, we are estimating the QAPI coordinators document the projects being conducted, the reason for the projects, and the measurable progress on these projects.

Requirement	Number of personnel per hospital	Annual hours per hospital	Number of hospitals	Annual hours
PIP Documentation	Coordinator	32 hours	6,069	194,208
Subtotal				194,208

Section 482.21(e) Standard: Executive Responsibilities

The participating hospitals must have in writing by-laws governing the medical staff and the governing body. This incorporation of executive responsibilities pertaining to QAPI would be a one-time development by an administrative team consisting of medical staff or an appointed committee of 5 physicians and one clerical personnel. We are not associating burden with this requirement, as by-laws should be updated regularly as a normal function of the hospital. This requirement is necessary to patient health and safety because the by-laws provide the framework within which all patient care services are furnished. The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in § 482.21.

If you have any comments on any of the information collection and record keeping requirements, please mail the original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group Division of CMS Enterprise, Standards Room N2–14–26, 7500 Security Blvd., Baltimore, Maryland 21244–1850, *Attention:* John Burke CMS–3050–F; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attention:* Brenda Aguilar, CMS Desk Officer CMS–3050–F.

List of Subjects in 42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this final rule, 42 CFR chapter IV is amended as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

2. In §482.21 the heading and text are revised to read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for

operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93778, Medical Assistance)

Dated: March 28, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 23, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–1293 Filed 1–23–03; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 21 and 101

[ET Docket No. 00–258; FCC 02–304]

Advanced Wireless Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allocates spectrum for advanced services in the 1710–1755 MHz, 2110–2150–MHz, and 2150–2155 MHz bands. The goal of this document is to promote the provision of advanced wireless services to the public, which supports the Commission's obligations under section 706 of the 1996 Telecommunication Act.

DATES: Effective February 24, 2003.

FOR FURTHER INFORMATION CONTACT: Jamison Prime, Office of Engineering and Technology, (202) 418–7474.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Report and Order,* ET Docket No. 00–258, FCC 02–304, adopted November 7, 2002, and released November 15, 2002. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Summary of the Second Report and Order

1. This *Second Report and Order* allocated 90 MHz of spectrum in the 1710–1755 MHz and 2110–2155 MHz bands that can be used for Advanced Wireless Service (AWS). This spectrum comes from bands that the Commission previously identified as candidate bands for the provision of AWS, and includes spectrum used by Federal government entities that is slated for transfer to non-Federal government use, spectrum currently used by fixed microwave services and designated for emerging technologies, and spectrum currently used by the Multipoint Distribution Service (MDS).

Spectrum for AWS

2. 1710–1755 MHz—The 1710–1755 MHz band was initially identified in 1995 for transfer from Federal government use to mixed Federal government/non-Federal government use. At that time, National Telecommunications Information Administration (NTIA) determined that this band could be made available to non-Federal government users in 2004. NTIA also identified certain incumbent Federal government facilities that may continue to operate in the band and must be protected from interference. In its *2002 Viability Assessment,* NTIA outlined additional steps for reaccommodating existing Federal government users in the band segment, including some that have a right to remain in the band indefinitely. The NTIA plan offered a mechanism that could largely clear the band of Federal government users no later than December 31, 2008.

3. Commenters note that the 1710–1755 MHz band enjoys many characteristics that make it suitable for AWS. They note it is already being used in many countries for 2G-style wireless services so it is likely to promote global spectrum harmonization in the long term, which in turn will foster roaming, and economies of scale that can translate into lower development costs and manufacturing efficiencies. They further state that this band can also help ensure that United States residents enjoy the same level of advanced services as in other countries. The parties observe that the 1710–1755 MHz band is slated to be made available for non-Federal Government commercial use, and that the *2002 Viability Assessment* offers a plan that can make the band even more useful for AWS. Catholic Television Network also states that the band ''offers better propagation characteristics,'' than other bands under consideration. We also note that the band size—45 megahertz would provide flexibility to accommodate a variety of channelization plans.

4. We find that it serves the public interest to allocate the 1710–1755 MHz band segment for mobile and fixed services on a co-primary basis contingent on its becoming available for non-Federal government mixed use January 1, 2004. In addition, we are removing the fixed and mobile allocations from the Federal government Table in the 1710–1755 MHz band, except as specified in the new United States footnote US378, which codifies Federal government residual rights. We also retain and modify footnote US311 in the Table of Frequency Allocations. This footnote identifies certain pre-existing radio astronomy activities that exist between 1718.8 MHz and 1722.2 MHz at observatories set forth in Appendix F of the *Notice of Proposed Rule Making* (NPRM) 66 FR 7438, January 23, 2001. Because radio astronomy facilities in this band operate on an unprotected basis, we conclude that it is not necessary to add rules setting forth coordination procedures and exclusion zones, as the National Academies of Science (NAS) suggests. The footnote, modified to update the list of radio astronomy facilities, will serve to apprise parties of these operations.

5. 2110–2150/2150–2155 MHz—Currently, the 2110–2150 band is used in the United States primarily for non-Federal Government fixed and mobile services licensed under the Fixed Microwave Service in part 101 of the rules, the Public Mobile Services under part 22 of the rules, and the Domestic Public Fixed Radio Services under part 21 of the rules. Federal government use of this band is generally on a secondary basis and is limited to space research earth stations for earth-to-space transmissions in the 2110–2120 MHz portion of the band. The Commission

originally identified this band for new advanced fixed and mobile services in the 1992 *Emerging Technologies* proceeding and adopted rules and procedures to permit new licensees to relocate existing fixed service microwave licensees from this spectrum band.

6. The 2110–2150 MHz band is already allocated to the fixed and mobile services on a primary basis, and thus it is not necessary that we reallocate this spectrum in order to make it available for AWS use. Instead we re-designate the band for new uses consistent with the general outline of our *Emerging Technologies* proceeding. We also note that the Balanced Budget Act of 1997 (BBA–97) identifies the 2110–2150 MHz band for advanced wireless use and specifies that the band must be assigned under the competitive bidding procedures.

7. In addition, we note that the National Aeronautical and Space Administration (NASA) operates on a primary basis a station in the 2110–2120 MHz band at Goldstone, California as part of the Space Research service. This station, which is authorized via United States footnote US252, is used by NASA's Deep Space Network (DSN) for uplink transmissions to interplanetary spacecraft. In the *NPRM,* we proposed not to relocate this facility. Moreover, the DSN earth station transmits with a nominal EIRP of 105.5 dBW. In the NPRM, we noted that during command link operations it is likely that mobile receivers on the 2110–2120 MHz segment (and possibly in adjacent bands above 2120 MHz) will not be able to operate within the areas surrounding Goldstone.

8. We examined the interference characteristics of the Goldstone DSN facility and based on its typical operation pattern, which is intermittent, the amount of its signal that would be blocked by terrain in many directions, and the low population density in the areas near Goldstone, we conclude that a significant amount of interference should not occur to AWS. Therefore, we will not formally restrict use of the 2110–2120 MHz band in the vicinity of Goldstone. However, we anticipate that this band will be unusable for advanced services at certain times in the immediate vicinity of Goldstone, and expect that potential licensees will take this fact into account and will develop their business and service plans accordingly. We believe that such an approach is practical, given the comments of the AWS proponents that discussed Goldstone interference, and we will work cooperatively with JPL and other interested parties to insure that our approach does in fact achieve its goals.

9. The 2150–2160 MHz band is allocated internationally to the fixed and mobile services on a primary basis and is regulated under part 21 of our rules as part of MDS. This band is generally operated as two channels—Channel 1 (2150–2156 MHz) and Channel 2A (2156–2160 MHz). In addition, licensees may use channel 2 (2156–2162 MHz) on a limited basis in 50 cities. MDS may also use spectrum in the 2500–2690 MHz band.

10. The Commission concludes that the record supports reallocation of 5 megahertz of spectrum at 2150–2155 MHz to add a mobile allocation to support the provision of AWS. Because this spectrum is contiguous to the 2110–2150 MHz band, this reallocation will allow efficiencies in deploying new AWS. For example, there will be only one point where AWS and MDS bands are adjacent and interference issues will need to be addressed. We note that the 2150–2155 MHz band is part of the ''worldwide'' IMT–2000 base station transmit band that extends from 2110 MHz to 2170 MHz. Thus our action here more closely aligns U.S. spectrum with allocations in the rest of the world and could lead to lower equipment costs and promote global roaming. Furthermore, this action will provide two contiguous 45 megahertz blocks of paired spectrum (*i.e.*, 1710–1755 MHz paired with 2110–2155 MHz), and provide more options for assigning large spectrum blocks suitable for AWS use.

11. The Commission recognizes that our decision here to reallocate the 2150–2155 MHz band from MDS to AWS use requires that we address certain issues regarding MDS operations. In particular, we will have to consider relocation spectrum and propose relocation procedures for MDS, keeping in mind the need to avoid disruption to existing customers. Because we do not anticipate licensing the band for new services until after we adopt service rules, and because the companion Federal government transfer spectrum in the 1710–1755 MHz band will not be available until 2004, there is sufficient time for us to identify in a separate proceeding to be initiated in the near future any necessary relocation spectrum for MDS licensees and to craft appropriate relocation procedures. In addressing relocation, however, we recognize the importance of avoiding unnecessary delay so as to minimize uncertainty to existing licensees.

12. We now turn to the relocation procedures for incumbent fixed microwave service licensees that currently operate in the 2110–2150 MHz band. Because this band was identified and reallocated for new uses in the *Emerging Technologies* proceeding, a mechanism already exists to clear these incumbent licensees. In the *NPRM,* we noted that fixed microwave service incumbents holding primary status (*see Second Report and Order, footnote 149*), in the 2110–2150 MHz band are entitled to compensation for relocation of facilities under these policies. *See Emerging Technologies Third Report and Order and Memorandum Opinion and Order,* 8 FCC Rcd 6589 (1993) 58 FR 46547, September 2, 1993. New licensees may relocate incumbent licensees' systems at their option. In general, a new licensee will relocate an incumbent system if it determines that the incumbent system will cause interference to the new licensee's system. The main elements of the relocation process include a set negotiation period or periods, usually triggered at the request of the new licensee; a requirement that the parties negotiate in good faith during the mandatory negotiation period; and the right of the incumbent to be relocated to comparable facilities at the expense of the new licensee. The relocation compensation includes all engineering, equipment, site, and FCC fees. The new licensee must complete all activities necessary for implementing the replacement facilities, and must test the new facilities to ensure comparability with the existing facilities. *See generally* 47 CFR 101.69 through 101.99. We further noted that certain fixed microwave incumbents in the 2110–2150 MHz band segment consist of links that are paired with frequencies in the 2165–2200 MHz band, which was previously reallocated to support MSS. Moreover, some microwave licensees at 2110–2115 MHz have paired links in the 2160–2165 MHz band.

13. In the *NPRM,* we noted that it would be possible for both relocation procedures to apply to the same new entrant in the 2110–2150 MHz band—the modified MSS relocation procedure for a link paired between the 2110–2150 MHz and 2165–2200 MHz bands and the *Emerging Technologies* procedure for all other relocations (including the relocation of a link paired between the 2110–2150 MHz and 2160–2165 MHz bands). We thus proposed to use the modified procedure for the relocation of any incumbent user in order to provide a single relocation process for this band. For microwave links paired in the 2110–2150 and 2160–2165 MHz bands, a new licensee would be required to relocate both paths (if such a relocation had not yet been done), but would retain a right

to seek reimbursement of 50 percent of its relocation costs from the licensee that ultimately uses frequencies in the second path. All new licensees, regardless of whether they relocate paired or unpaired microwave incumbents, would be subject to the modified relocation rules (such as the shortened mandatory negotiation period).

14. We conclude that the modified relocation procedures, as proposed, represent the best course. A unified approach to our rules and procedures serves the public interest, and can promote the rapid development of AWS, which many commenters support. Moreover, if the demand for the advanced services is as robust as commenters claim, incumbent licensees should find new licensees particularly eager to reach relocation agreements so as not to be competitively disadvantaged by a delay in their service deployment. Finally, we note that under our basic relocation principles, incumbents retain a right to comparable facilities. We stress that we are not altering this process, nor an incumbent's right to seek relief if it believes the relocation process has not been conducted in good faith. We observe, however, that we may need to modify the reimbursement provisions if MDS is reassigned to the 2155–2165 MHz band because Fixed Service microwave operations in the 2160–2165 MHz band would have to be relocated. Under the current rules, for example, MDS would have to reimburse a new AWS entrant who is trying to clear paired microwave links at 2110–2115 and 2160–2165 MHz.

Other Bands

15. 1755–1850 MHz. In the *NPRM,* we identified the 1755–1850 MHz band for consideration for the provision of AWS. The 1755–1770 MHz band segment was considered as part of the initial NTIA studies, and was again evaluated in the *2002 Viability Assessment.* In this most recent review, NTIA concluded that the 1755–1850 MHz band is not viable for use by AWS due to the extensive and critical Federal Government operations in the band, including DOD mobile systems operating in the 1755–1850 MHz range that ''have recently been elevated in importance due [to] the war on terrorism, homeland defense, and possible requirements for ballistic missile defense.'' Moreover, NTIA was unable to identify alternative spectrum bands that could readily accommodate many of these systems, including air combat training systems, the Land Warrior systems, and DOD satellite telemetry, tracking and command facilities that operate in the 1761–1842 MHz band segment and which cannot be easily re-tuned. The 1770–1850 MHz band segment was previously rejected by NTIA as incompatible for shared use and was not included in the most recent band evaluation process. Throughout the evaluation process, Federal Government users have consistently expressed skepticism that any portion of the 1755–1850 MHz band segment can be made available for advanced commercial wireless systems, either through relocation of Federal users or by shared use. Moreover, NTIA anticipates that the process that will allow it to relocate Federal users from the 1710–1755 MHz band segment will result in system relocations to spectrum above 1755 MHz, as well as a generally more intensive use of the 1770–1850 MHz band segment for existing, relocated, and new systems. We note that some commenters identify benefits from the use of this band for AWS, including regional harmonization and the possibility that allocation of the 1755–1850 MHz band (in conjunction with the 1710–1755 MHz band) would serve as a catalyst for making these frequencies as globally accepted as the core bands identified in IMT–2000.

16. Given the statements by NTIA regarding the intense use of this band by military users and other Federal Government agencies that provide critical safety-of-life operations, and the concern expressed by many commenters about clearing existing government users, we conclude that this band is too encumbered to be used for the provision of AWS. We note that while some comments suggest that we explore a combination of sharing and migration for incumbent users, NTIA and other commenters do not believe that co-channel sharing is possible. We acknowledge the *2002 Viability Assessment's* conclusion that ''[a] leap forward in technology may permit extensive sharing in all bands below 3 GHz in the future,'' but that until such developments occur, it appears that use of the 1755–1770 MHz band for advanced wireless applications is not technically viable. Accordingly, we conclude that the 1755–1850 MHz band is not suitable for the provision of AWS at this time.

17. Currently Allocated Spectrum. In the *NPRM*, we noted that currently allocated spectrum may also be suitable for the provision of AWS. This spectrum includes television bands that were reallocated to commercial fixed, mobile, and broadcast services and are in the process of being vacated as part of the transition to digital television. We note that the disposition of these bands has taken place in separate proceedings. The record in the instant proceeding contains nothing that would cause us to revisit these decisions, nor to reassess our general conclusion that the reallocated television bands will be available for new uses, including AWS. However, we reach an opposite conclusion with respect to the 2390–2400 MHz band. The record reflects little support for AWS use of this band, which is designated for UPCS and Amateur Service use, and the *2002 Viability Assessment* identified this spectrum as suitable replacement spectrum for some Government systems currently operating in the 1710–1755 MHz band. Therefore, we will not further examine the possible use of the 2390–2400 MHz band for the provision of AWS.

18. The 90 megahertz of spectrum that has been allocated will promote the robust deployment of AWS, and we will continue to strive to make allocation decisions that can lead to the widescale deployment of innovative new services. Moreover, technological developments may foster further efficiencies in the deployment of AWS. These technologies include software defined radio (SDR) and adaptive antenna technology (increasing directionality) or new modulation or coding techniques (more information in the same spectrum) that may allow for greater spectral efficiency than that which is typically associated with current wireless systems. Finally, we stress that this action is part of a continuing effort to identify and evaluate both the current and future spectrum needs for AWS. The further decisions that we make in this continuing proceeding may well result in the allocation of additional spectrum for commercial use, including the provision of AWS.

Final Regulatory Flexibility Analysis

19. As required by the Regulatory Flexibility Act (RFA)[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking and Order* (NPRM),[2] as well as the *Memorandum Opinion and Order and Further Notice of Proposed Rule Making* (Further NPRM), 66 FR 47591, September 13,

[1] *See* 5 U.S.C. 603. The RFA (codified at 5 U.S.C. 601–612) has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, title II, 110 Stat. 857 (1996).

[2] Amendment of part 2 of the Commission's rules to Allocate Spectrum Below 3 GHz for Mobile and Fixed Services to Support the Introduction of New Advanced Wireless Services, Including Third Generation Wireless Systems, ET Docket No. 00–258, *Notice of Proposed Rulemaking and Order,* 16 FCC Rcd 596 (2001).

2001.[3] The Commission sought written public comments on the proposals in the *NPRM* and *Further NPRM,* including comment on each IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[4]

Need for, and Objectives of, the Second Report and Order

20. The goal of the *Second Report and Order* (Second R&O) is to promote the provision of advanced wireless services (AWS) to the public, which in turn supports our obligations under section 706 of the 1996 Telecommunication Act[5] and, more generally, serves the public interest by promoting rapid and efficient radio communication facilities.

21. The *Second R&O* discusses the need for spectrum allocations of sufficient size and with particular characteristics so as to allow for the provision of AWS, and evaluates spectrum that could be allocated to support these services. Specifically, the *Second R&O* allocates spectrum that is suitable for advanced services in the 1710–1755 MHz, 2110–2150 MHz, and 2150–2155 MHz bands.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

22. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

23. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the rules adopted herein.[6] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[7] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[8] A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).[9]

24. A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[10] Nationwide, as of 1992, there were approximately 275,801 small organizations.[11] ''Small governmental jurisdiction'' generally means ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.''[12] As of 1992, there were approximately 85,006 governmental entities in the United States.[13] This number includes 38,978 counties, cities, and towns; of these, 37,566, or 96%, have populations of fewer than 50,000.[14] The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (96%) are small entities.

25. *Fixed Microwave Services.* Microwave services include common carrier,[15] private-operational fixed,[16] and broadcast auxiliary radio services.[17] At present, there are approximately 22,015 common carrier fixed licensees and 61,670 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. The Commission has not yet defined a small business with respect to microwave services. For purposes of this FRFA, we will use the SBA's definition applicable to wireless and other telecommunications companies—*i.e.*, an entity with no more than 1,500 persons.[18] According to Census Bureau data for 1997, there were 977 firms in this category, total, that operated for the entire year.[19] Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more.[20] Thus, under this size standard, the great majority of firms can be considered small.

26. We note that the number of firms does not necessarily track the number of licensees. We estimate that all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition. Of these licenses, approximately 8,210 are issued for frequencies in the *Emerging Technologies* bands affected by this proceeding. In addition, these bands contain approximately 70 licenses in the paging and radiotelephone service and the general aviation and air-ground radio telephone services. Thus, assuming that these entities also qualify as small businesses, as many as 8,280 small business licensees could be affected by the rules we adopt. We note that these entities have been subject to relocation under rules originally adopted ten years ago in the Commission's *Emerging Technologies* proceeding. The *Second Report and Order* anticipates that these general relocation rules will continue to apply to FS microwave licensees and does not modify the class of licensees that are subject to these relocation provisions.

27. *Multipoint Distribution Service (MDS).* This service has historically provided primarily point-to-multipoint, one-way video services to subscribers, and Local Multipoint Distribution Service (LMDS).[21] The Commission

[3] Amendment of part 2 of the Commission's rules to Allocate Spectrum Below 3 GHz for Mobile and Fixed Services to Support the Introduction of New Advanced Wireless Services, including Third Generation Wireless Systems, ET Docket No. 00–258, ET Docket No. 95–18, and IB Docket No. 99–81, *Memorandum Opinion and Order and Further Notice of Proposed Rule Making,* 16 FCC Rcd 16043 (2001) 66 FR 47591, September 13, 2001.

[4] *See* 5 U.S.C. 604.

[5] Section 706 of the Communications Act of 1934, as amended, codified at 47 U.S.C. 157.

[6] 5 U.S.C. 604(a)(3).

[7] 5 U.S.C. 601(6).

[8] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small-business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[9] 15 U.S.C. 632.

[10] 5 U.S.C. 601(4).

[11] Department of Commerce, U.S. Bureau of the Census, 1992 Economic Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

[12] 5 U.S.C. 601(5).

[13] U.S. Dept. of Commerce, Bureau of the Census, ''1992 Census of Governments.''

[14] *Id.*

[15] 47 CFR 101 *et seq.* (formerly, part 21 of the Commission's rules).

[16] Persons eligible under parts 80 and 90 of the Commission's rules can use Private Operational-Fixed Microwave services. *See* 47 CFR parts 80 and 90. Stations in this service are called operational-fixed to distinguish them from common carrier and public fixed stations. Only the licensee may use the operational-fixed station, and only for communications related to the licensee's commercial, industrial, or safety operations.

[17] Auxiliary Microwave Service is governed by part 74 of title 47 of the Commission's rules. *See* 47 CFR part 74 *et seq.* Available to licensees of broadcast stations and to broadcast and cable network entities, broadcast auxiliary microwave stations are used for relaying broadcast television signals from the studio to the transmitter, or between two points such as a main studio and an auxiliary studio. The service also includes mobile TV pickups, which relay signals from a remote location back to the studio.

[18] 13 CFR 121.201, NAICS code 517212 (formerly 513322).

[19] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Employment Size of Firms Subject to Federal Income Tax: 1997,'' Table 5, NAICS code 517212 (issued Oct. 2000).

[20] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is ''Firms with 1,000 employees or more.''

[21] For purposes of this item, MDS includes single channel Multipoint Distribution Service (MDS) and

recently amended its rules to allow MDS licensees to provide a wide range of high-speed, two-way services to a variety of users.[22] In connection with the 1996 MDS auction, the Commission defined small businesses as entities that had annual average gross revenues for the three preceding years not in excess of $40 million.[23] The Commission established this small business definition in the context of this particular service and with the approval of the SBA.[24] The MDS auction resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs).[25] Of the 67 auction winners, 61 met the definition of a small business. At this time, we estimate that of the 61 small business MDS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent MDS licensees that are considered small entities.[26] After adding the number of small business auction licensees to the number of incumbent licensees not already counted, we find that there are currently approximately 440 MDS licensees that are defined as small businesses under either the SBA or the Commission's rules. Because the Commission's action only affects MDS operations in the 2150–2155 MHz band, the actual number of MDS providers who will be affected by the *Second Report and Order* will only represent a small fraction of those 440 small business licensees.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

28. The *Second R&O* addressed the possible use of frequency bands below 3 GHz to support the introduction of new AWS, but does not propose service rules. Thus, the item contains no new reporting, recordkeeping, or other compliance requirements. Because the item does not establish procedures for the relocation of MDS incumbents from the 2150–2155 MHz band, there are no new compliance requirements for MDS at this time.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

29. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''[27]

30. Providing spectrum to support the introduction of new advanced mobile and fixed terrestrial wireless services is critical to the continuation of technological advancement. First and foremost, the Commission believes that our proposal to explore the possible use of several frequency bands that could offer a wide range of voice, data, and broadband services over a variety of mobile and fixed networks may provide substantial new opportunities for small entities.

31. However, we realize that some entities must be displaced to clear a sufficient quantity of contiguous spectrum to support new services. We endeavored to avoid this effect by identifying unencumbered spectrum, but spectrum in the suitable frequency range is heavily used already and a sufficient amount of unencumbered spectrum simply does not exist. We have therefore sought to minimize an adverse impact by proposing to reallocate frequency bands for those incumbents, including small entities, which might be accommodated in other spectrum and could be relocated more easily. The spectrum we allocate in the 1710–1755 MHz band is currently used for Federal government services, and therefore there are no non-Federal government incumbent small entities that will be displaced by the reallocation of this band. Similarly, as noted in paragraph 28 of the *Second R&O*, the 2110–2150 MHz band was previously identified as an Emerging Technology band, and relocation procedures already exist for incumbents in this band. These existing procedures (as modified in the *Second R&O*) should serve to ease the relocation of small entity incumbents in the 2110–2150 MHz band, and make reallocation of this band preferable to the reallocation of other bands where we would have to establish new relocation rules.

32. Finally, the Commission has already received extensive comments in this proceeding on issues related to the possible reallocation of the 2150–2160 MHz (2.1 GHz) spectrum for advanced wireless purposes. Comments filed by the multipoint distribution/instructional television fixed services industry and several equipment manufacturers argue that the 2.1 GHz band is necessary for the continued roll-out of fixed wireless services across the country. Other commenters support the use of 2.1 GHz for advanced wireless services. Although many commenters ask that we reallocate a large contiguous spectrum block to include the entire 2150–2160 MHz band, we instead decide to reallocate 5 megahertz in the 2150–2160 MHz band as part of a 45 megahertz block of contiguous spectrum that can be used to provide advanced services. By doing so, we satisfy the need to designate a large block of contiguous spectrum that can be paired in order to allow for the deployment of advanced services (and thus, serve the goals of this proceeding). However, by allocating 5 megahertz of existing MDS spectrum, we retain greater flexibility to accommodate small entities that are MDS licensees than had we redesignated the entire 2.1 GHz MDS spectrum. For example, paragraph 39 of the *Second Report and Order*, notes that we retain the option to realign MDS spectrum to a 10 megahertz block in the 2155–2165 MHz band. Had we reallocated the entire 2.1 GHz MDS spectrum, as some commenters had suggested, this option would not have been available.

Report to Congress

33. The Commission will send a copy of the *Second Report and Order* including this FRFA, in a report to be sent to Congress pursuant to the

the Multichannel Multipoint Distribution Service (MMDS). *See* 66 FR 36177.

[22] Amendment of parts 21 and 74 to Enable Multipoint Distribution Service and Instructional Television Fixed Service Licensees to Engage in Fixed Two-Way Transmissions, MM Docket No. 97–217, *Report and Order,* 13 FCC Rcd 19112 (1998), *recon.,* 14 FCC Rcd 12764 (1999), *further recon.,* 15 FCC Rcd 14566 (2000).

[23] 47 CFR 21.961 and 1.2110.

[24] Amendment of parts 21 and 74 of the Commission's Rules with Regard to Filing Procedures in the Multipoint Distribution Service and in the Instructional Television Fixed Service and Implementation of Section 309(j) of the Communications Act—Competitive Bidding, MM Docket No. 94–131, *Report and Order,* 10 FCC Rcd 9589, 9670 (1995), 60 FR 36524 (July 17, 1995).

[25] Basic Trading Areas (BTAs) were designed by Rand McNally and are the geographic areas by which MDS was auctioned and authorized. *See id.* at 9608.

[26] 47 U.S.C. 309(j). (Hundreds of stations were licensed to incumbent MDS licensees prior to implementation of section 309(j) of the Communications Act of 1934, 47 U.S.C. 309(j)). For these pre-auction licenses, the applicable standard is SBA's small business size standard for ''other telecommunications'' (annual receipts of $12.5 million or less). *See* 13 CFR 121.201.

[27] 5 U.S.C. 603(c)(1) through (c)(4).

Congressional Review Act.[28] In addition, the Commission will send a copy of the Second Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA.

Ordering Clauses

34. Pursuant to sections 1, 4(i), 7(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151, 154(i), 157(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, and 332 the Second Report and Order is hereby adopted. The rules set forth will become effective February 24, 2003.

35. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Second Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

[28] *See* 5 U.S.C. 801(a)(1)(A).

List of Subjects

47 CFR Part 2

Communications equipment.

47 CFR Part 21

Communications equipment, Radio.

47 CFR Part 101

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2, 21, and 101 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

2. Section 2.106, the Table of Frequency Allocations, is amended as follows:

a. Revise pages 47 and 49.

b. In the list of United States (US) Footnotes, remove footnote US256, revise footnote US311, and add footnote US378.

c. In the list of non-Federal Government (NG) Footnotes, revise footnote NG153 and add footnote NG176.

§ 2.106 Table of Frequency Allocations.

The revisions and additions read as follows:

* * * * *

BILLING CODE 6712–01–P

International Table			United States Table		FCC Rule Part(s)
Region 1	Region 2	Region 3	Federal Government	Non-Federal Government	
1670-1675 METEOROLOGICAL AIDS FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE 5.380 5.341			1670-1675 5.341 US211 US362	1670-1675 FIXED MOBILE except aeronautical mobile 5.341 US211 US362	Wireless Communications (27)
1675-1690 METEOROLOGICAL AIDS FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile 5.341	1675-1690 METEOROLOGICAL AIDS FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile MOBILE-SATELLITE (Earth-to-space) 5.341 5.377	1675-1690 METEOROLOGICAL AIDS FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile 5.341	1675-1700 METEOROLOGICAL AIDS (radiosonde) METEOROLOGICAL-SATELLITE (space-to-Earth) 5.289 5.341 US211		
1690-1700 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) Fixed Mobile except aeronautical mobile 5.289 5.341 5.382	1690-1700 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (Earth-to-space) 5.289 5.341 5.377 5.381	1690-1700 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) 5.289 5.341 5.381			
1700-1710 FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile 5.289 5.341	1700-1710 FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile MOBILE-SATELLITE (Earth-to-space) 5.289 5.341 5.377	1700-1710 FIXED METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile 5.289 5.341 5.384	1700-1710 FIXED G118 METEOROLOGICAL-SATELLITE (space-to-Earth) 5.289 5.341	1700-1710 METEOROLOGICAL-SATELLITE (space-to-Earth) Fixed 5.289 5.341	
1710-1930 FIXED MOBILE 5.380 5.384A 5.388A			1710-1755 5.341 US311 US378	1710-1755 FIXED MOBILE 5.341 US311 US378 NG176	

2110-2345 MHz (UHF) Page 49

International Table			United States Table		FCC Rule Part(s)
Region 1	Region 2	Region 3	Federal Government	Non-Federal Government	
2110-2120 FIXED MOBILE 5.388A SPACE RESEARCH (deep space) (Earth-to-space) 5.388			2110-2120 US252	2110-2155 FIXED NG23 MOBILE US252	Public Mobile (22) Fixed Microwave (101)
2120-2160 FIXED MOBILE 5.388A 5.388	2120-2160 FIXED MOBILE 5.388A Mobile-satellite (space-to-Earth) 5.388	2120-2160 FIXED MOBILE 5.388A 5.388	2120-2200	2155-2160 FIXED NG23	Domestic Public Fixed (21) Fixed Microwave (101)
2160-2170 FIXED MOBILE 5.388A 5.388 5.392A	2160-2170 FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.388 5.389C 5.389D 5.389E 5.390	2160-2170 FIXED MOBILE 5.388A 5.388		2160-2165 FIXED NG23 NG153 MOBILE	Domestic Public Fixed (21) Public Mobile (22) Fixed Microwave (101)
2170-2200 FIXED MOBILE MOBILE-SATELLITE (space-to-Earth) 5.351A 5.388 5.389A 5.389F 5.392A				2165-2200 MOBILE-SATELLITE (space-to-Earth) NG23 NG168	Satellite Communications (25)
2200-2290 SPACE OPERATION (space-to-Earth) (space-to-space) EARTH EXPLORATION-SATELLITE (space-to-Earth) (space-to-space) FIXED MOBILE 5.391 SPACE RESEARCH (space-to-Earth) (space-to-space)			2200-2290 SPACE OPERATION (space-to-Earth) (space-to-space) EARTH EXPLORATION- SATELLITE (space-to- Earth) (space-to-space) FIXED (line-of-sight only)	2200-2290	

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United States (US) Footnotes

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US311 Radio astronomy observations may be made in the bands 1350–1400 MHz, 1718.8–1722.2 MHz, and 4950–4990 MHz on an unprotected basis at the following radio astronomy observatories:

Allen Telescope Array, Hat Creek, California	Rectangle between latitudes 40° 00′ N and 42° 00′ N and between longitudes 120° 15′ W and 122° 15′ W.	
NASA Goldstone Deep Space Communications Complex, Goldstone, California.	80 kilometers (50 mile) radius centered on latitude 35° 18′ N, longitude 116° 54′ W.	
National Astronomy and Ionosphere Center, Arecibo, Puerto Rico	Rectangle between latitudes 17° 30′ N and 19° 00′ N and between longitudes 65° 10′ W and 68° 00′ W.	
National Radio Astronomy Observatory, Socorro, New Mexico	Rectangle between latitudes 32° 30′ N and 35° 30′ N and between longitudes 106° 00′ W and 109° 00′ W.	
National Radio Astronomy Observatory, Green Bank, West Virginia	Rectangle between latitudes 37° 30′ N and 39° 15′ N and between longitudes 78° 30′ W and 80° 30′ W.	
National Radio Astronomy Observatory, Very Long Baseline Array Stations.	80 kilometer radius centered on:	
	Latitude (North)	Longitude (West)
Brewster, WA	48° 08′	119° 41′
Fort Davis, TX	30° 38′	103° 57′
Hancock, NH	42° 56′	71° 59′
Kitt Peak, AZ	31° 57′	111° 37′
Los Alamos, NM	35° 47′	106° 15′
Mauna Kea, HI	19° 48′	155° 27′
North Liberty, IA	41° 46′	91° 34′
Owens Valley, CA	37° 14′	118° 17′
Pie Town, NM	34° 18′	108° 07′
Saint Croix, VI	17° 46′	64° 35′
Owens Valley Radio Observatory, Big Pine, California	Two contiguous rectangles, one between latitudes 36° 00′ N and 37° 00′ N and between longitudes 117° 40′ W and 118° 30′ W and the second between latitudes 37° 00′ N and 38° 00′ N and between longitudes 118° 00′ W and 118° 50′ W.	

In the bands 1350–1400 MHz and 4950–4990 MHz, every practicable effort will be made to avoid the assignment of frequencies to stations in the fixed and mobile services that could interfere with radio astronomy observations within the geographic areas given above. In addition, every practicable effort will be made to avoid assignment of frequencies in these bands to stations in the aeronautical mobile service which operate outside of those geographic areas, but which may cause harmful interference to the listed observatories. Should such assignments result in harmful interference to these observatories, the situation will be remedied to the extent practicable.

* * * * *

US378 In the band 1710–1755 MHz, Federal government stations in the fixed and mobile services shall operate on a primary basis until reaccommodated in accordance with the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. Further, Federal government stations may continue to operate in the band 1710–1755 MHz as provided below:

(a) Federal fixed microwave and tactical radio relay stations may operate indefinitely on a primary basis at the sites listed below:

Location	Coordinates	Radius of operation (km)
Cherry Point, NC	34° 58′ N 076° 56′ W	80
Yuma, AZ	32° 32′ N 113° 58′ W	80

(b) Federal fixed microwave and tactical radio relay stations may operate on a secondary basis, and shall not cause harmful inference to, and must accept harmful interference from, primary non-Federal government operations at the sites listed below:

Location	Coordinates	Radius of operation (km)
China Lake, CA	35° 41′ N 117° 41′ W	80
Eglin AFB, FL	30° 29′ N 086° 31′ W	80

Location	Coordinates	Radius of operation (km)
Pacific Missile Test Range/Point Mugu, CA	34° 07′ N 119° 30′ W	80
Nellis AFB, NV	36° 14′ N 115° 02′ W	80
Hill AFB, UT	41° 07′ N 111° 58′ W	80
Patuxent River, MD	38° 17′ N 076° 25′ W	80
White Sands Missile Range, NM	33° 00′ N 106° 30′ W	80
Fort Irwin, CA	35° 16′ N 116° 41′ W	50
Fort Rucker, AL	31° 13′ N 085° 49′ W	50
Fort Bragg, NC	35° 09′ N 079° 01′ W	50
Fort Campbell, KY	36° 41′ N 087° 28′ W	50
Fort Lewis, WA	47° 05′ N 122° 36′ W	50
Fort Benning, GA	32° 22′ N 084° 56′ W	50
Fort Stewart, GA	31° 52′ N 081° 37′ W	50

(c) In the sub-band 1710–1720 MHz, precision guided munitions shall operate on a primary basis until inventory is exhausted or until December 31, 2008, whichever is earlier.

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Non-Federal Government (NG) Footnotes

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NG153 The band 2160–2165 MHz is reserved for future emerging technologies on a co-primary basis with the fixed and mobile services. Allocations to specific services will be made in future proceedings. Authorizations in the band 2160–2162 MHz for stations in the Multipoint Distribution Service applied for after January 16, 1992, shall be on a secondary basis to emerging technologies.

* * * * *

NG176 The allocations to the fixed and mobile services in the band 1710–1755 MHz shall come into effect on January 1, 2004.

PART 21—DOMESTIC PUBLIC FIXED RADIO SERVICES

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

Authority: Secs. 1, 2, 4, 201–205, 208, 215, 218, 303, 307, 313, 403, 404, 410, 602, 48 Stat. as amended, 1064, 1066, 1070–1073, 1076, 1077, 1080, 1082, 1083, 1087, 1094, 1098, 1102, 47 U.S.C. 151, 154, 201–205, 208, 215, 218, 303, 307, 313, 314, 403, 404, 602, 47 U.S.C. 552, 554.

§ 21.50 [Removed and reserved]

4. Remove and reserve § 21.50.

PART 101—FIXED MICROWAVE SERVICES

5. The authority citation for part 101 continues to read as follows:

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

6. Section 101.69 is amended by revising paragraph (d) introductory text to read as follows:

§ 101.69 Transition of the 1850–1990 MHz, 2110–2150 MHz, and 2160–2200 MHz bands from the fixed microwave services to personal communications services and emerging technologies.

* * * * *

(d) Relocation of FMS licensees in the 2110–2150 and 2160–2200 MHz bands will be subject to mandatory negotiations only. Mandatory negotiation periods are defined as follows:

* * * * *

7. Section 101.73 is amended by revising the first and second sentences in paragraph (d) introductory text and the first and second sentences in paragraph (d)(3) to read as follows:

§ 101.73 Mandatory negotiations.

* * * * *

(d) Provisions for Relocation of Fixed Microwave Licensees in the 2110–2150 and 2160–2200 MHz bands. Mandatory negotiations will commence when the ET licensee informs the fixed microwave licensee in writing of its desire to negotiate. * * *

* * * * *

(3) *Operating Costs.* Operating costs are the cost to operate and maintain the FMS system. ET licensees would compensate FMS licensees for any increased recurring costs associated with the replacement facilities (*e.g.*, additional rental payments, and increased utility fees) for five years after relocation. ET licensees could satisfy this obligation by making a lump-sum payment based on present value using current interest rates. * * *

* * * * *

8. Section 101.75 is amended by revising paragraph (d) to read as follows:

§ 101.75 Involuntary relocation procedures.

* * * * *

(d) *Twelve-month trial period.* If, within one year after the relocation to new facilities, the FMS licensee demonstrates that the new facilities are not comparable to the former facilities, the ET licensee must remedy the defects or pay to relocate the microwave licensee to one of the following: its former or equivalent 2 GHz channels, another comparable frequency band, a land-line system, or any other facility that satisfies the requirements specified in paragraph (b) of this section. This trial period commences on the date that the FMS licensee begins full operation of the replacement link. If the FMS licensee has retained its 2 GHz authorization during the trial period, it must return the license to the Commission at the end of the twelve months. FMS licensees relocated from the 2110–2150 and 2160–2200 MHz bands may not be returned to their former 2 GHz channels. All other remedies specified in paragraph (d) are available to FMS licensees relocated from the 2110–2150 MHz and 2160–2200 MHz bands, and may be invoked whenever the FMS licensee demonstrates that its replacement facility is not comparable, subject to no time limit.

9. Section 101.99 is amended by revising the section heading and paragraph (a) to read as follows:

§ 101.99 Reimbursement and relocation expenses in the 2110–2150 MHz and 2160–2200 MHz bands.

(a) Whenever an ET licensee (including Mobile-Satellite Service licensees) in the 2110–2150 or 2160–2200 MHz bands relocates an incumbent paired microwave link with one path in the 2110–2150 MHz band and the paired path in the 2160–2200 MHz band, the ET licensee is entitled to reimbursement of 50% of its relocation costs from any subsequently entering ET

licensee which would have been required to relocate the same fixed microwave link.

* * * * *

[FR Doc. 03–1457 Filed 1–23–03; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 801, 806, 812, 837, 852, and 873

RIN 2900–AI71

VA Acquisition Regulation: Simplified Acquisition Procedures for Health-Care Resources

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs Acquisition Regulation (VAAR) to establish simplified procedures for the competitive acquisition of health-care resources, consisting of commercial services or the use of medical equipment or space pursuant to statute. The Veterans' Health Care Eligibility Reform Act of 1996 authorized VA to prescribe simplified procedures for the procurement of health-care resources. This rule prescribes those procedures.

EFFECTIVE DATE: February 24, 2003.

FOR FURTHER INFORMATION CONTACT: Dennis Foley, (202) 273–9225, Office of the General Counsel, Professional Staff Group V; or Don Kaliher, (202) 273–8819, Acquisition Resources Service, Office of Acquisition and Materiel Management, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420.

SUPPLEMENTARY INFORMATION: On June 7, 2001, we published in the **Federal Register** (66 FR 30659) a proposed rule to amend the Department of Veterans Affairs Acquisition Regulation (VAAR), pursuant to 38 U.S.C. 8151–8153, to establish simplified procedures for the competitive acquisition of health-care resources consisting of commercial services or the use of medical equipment or space.

Comments were solicited concerning the proposal for 60 days, ending August 6, 2001. We did not receive any comments.

The information presented in the proposed rule document still provides a basis for this final rule. In addition, the proposed rule requested Paperwork Reduction Act (PRA) comments concerning the collection of information regarding clauses for use in both commercial and non-commercial item and service solicitations and contracts. No comments were received by VA or the Office of Management and Budget (OMB).

Therefore, based on the rationale set forth in the proposed rule document, we are adopting the provisions of the proposed rule as a final rule with no changes, except for a non-substantive change to reflect, at 48 CFR 801.301–70(c), the PRA clearance numbers assigned by OMB to clauses 852.207–70 and 852.237–7.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

Executive Order 12866

This document has been reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Analysis

This rule may have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. An Initial Regulatory Flexibility Analysis was published in the **Federal Register** on June 7, 2001, (66 FR 30672) as part of the proposed rule. No comments were received. As required by the RFA (5 U.S.C. 601 *et. seq.*), the following Final Regulatory Flexibility Analysis is set forth.

a. A succinct statement of the need for and the objectives of the rule.

Response: The rule amends the VAAR to implement the provisions of 38 U.S.C. 8151–8153, which authorize the Secretary of Veterans Affairs, in consultation with the Administrator of Federal Procurement Policy, to prescribe simplified procedures for the procurement of health-care resources. We believe the simplified procedures will allow VA to become more efficient in procuring health-care resources.

The objective of the rule is to allow VA to become more efficient in procuring health-care resources and thereby strengthen the medical programs of the Department and improve the quality of health care provided to veterans.

b. A summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the agency's assessment of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

Response: No public comments were received and no changes were made to the proposed rule.

c. A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

Response: The small entities that could be affected by the rule are any small entities that provide commercial services or the use of medical equipment or space to the health-care industry.

We do not have precise figures on the number of small entities that could potentially be affected by the rule. Any small entity that provides, or wishes to provide, commercial services or the use of medical equipment or space to VA health-care facilities could potentially be affected.

However, the rule will not apply to the majority of VA acquisitions. The rule applies only to competitive acquisitions of commercial services or the use of medical equipment or space conducted by the Veterans Health Administration (VHA) and which specifically reference the authority of 38 U.S.C. 8153. The rule does not apply to acquisitions of supplies or equipment made on behalf of VHA or to acquisitions made on behalf of the Veterans Benefits Administration (VBA) or the National Cemetery Administration (NCA). Except for section 873.108(b), the rule does not apply to VHA sole source acquisitions from affiliated institutions or entities associated with affiliated institutions. The authority for VHA to contract on a sole source basis with an institution affiliated with VA or with a medical practice group or other approved entity associated with an affiliate, addressed in the rule at 873.108(b), is authorized by law and is not dependent upon this rulemaking. The rule does not apply to acquisitions of services for which other specific authorities apply, such as acquisitions of nursing home care services, which are acquired under the authority of 38 U.S.C. 1720, or to acquisitions of non-commercial services, such as construction.

We have no relevant data regarding commercial service acquisitions below $25,000. However, we expect little application of the rule to acquisitions below $25,000. Existing FAR provisions for such acquisitions are already very simple and the provisions of the rule likely would not provide a significant benefit to the Government to warrant

use of this authority for such low dollar value acquisitions.

In Fiscal Year (FY) 1998, VHA reported approximately 6,000 individual service transactions valued in excess of $25,000 to the Federal Procurement Data System. This 6,000 figure excludes classification codes C, architect/engineer; E, purchase of structures; Q402, nursing home; Y, construction; and Z, maintenance of real property, all of which we believe are not covered by the rule. Of those 6,000 transactions, approximately 3,000 were awarded to small businesses and approximately 900 were awarded to non-profit businesses. Similar figures were reported for FY 1999. Of the total acquisition dollars associated with these 6,000 annual awards, we estimate that in FY 1998, approximately 42 percent, and in FY 1999, approximately 44 percent, were awarded to small businesses.

d. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement, and the type of professional skills necessary for preparation of the report or record.

Response: The reporting or recordkeeping requirements of the clauses at section 852.207–70, Report of employment under commercial activities, and section 852.237–7, Indemnification and Medical Liability Insurance, were discussed in the Paperwork Reduction Act (PRA) portion of the proposed rule, published in the **Federal Register** on June 7, 2001 (66 FR 30671). The clause at section 852.207–70 requires the contractor, on contracts where current VA employees are displaced, to report on employment openings and on efforts to hire displaced VA employees. The clause at section 852.237–7 requires contractors, on contracts for nonpersonal health-care services, to provide evidence of liability insurance. The final rule imposes no new reporting or recordkeeping requirements not already required by the VAAR. Currently, the VAAR requires that these clauses be included in all applicable solicitations and contracts, *i.e.,* contracts where VA employees might be displaced (852.207–70) or contracts for nonpersonal health-care services (852.237–7). The rule provides clarification that these clauses would continue to be required in all applicable service contracts, including commercial service contracts issued under the authority of 38 U.S.C. 8153. Small entities currently holding contracts where VA employees might be displaced or contracts for nonpersonal health-care services are required to provide employment reports or evidence of liability insurance, as applicable. Under the rule, there is no change to those requirements and no new added requirements. There are no additional small entities affected by the rule that would not already be affected by the current regulations. No professional skills are necessary to comply with these reporting and recordkeeping requirements.

e. A description of the steps the agency has taken to minimize the significant economic impacts on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule, and the reasons for rejecting each of the other significant alternatives.

Response: We believe that, with two exceptions (1. and 2. below), the provisions of the rule, where those provisions differ from the FAR, are small business/large business neutral, *i.e.*, they would have neither a positive nor a negative impact on small business or large business. The two exceptions concern the authority to waive FAR small business set-aside requirements and the provisions concerning the transmission of solicitation notices to the Governmentwide point of entry (GPE).

1. The rule at section 873.107 contains a provision allowing the head of the contracting activity (HCA) to waive the requirement to set aside an acquisition for small business. The HCA must determine that the waiver is in the best interest of the Government. The availability of this authority may result in acquisitions where small businesses have to compete against large businesses rather than compete only against other small businesses.

The alternatives to this waiver authority that were considered in order to limit the impact of the rule on small businesses included having no waiver authority, limiting the application of that authority to specific types of acquisitions, such as acquisitions for medical services, or limiting the authority to acquisitions in excess of a certain dollar threshold. For the reasons stated below, we determined to place no limits, other than those contained in the rule, on the application of this waiver authority.

As noted above, the rule would only apply to a limited number of acquisitions. We believe the waiver authority would be used in very few of those limited number of acquisitions, primarily in acquisitions where it is critical to broaden the pool of sources considered in order to obtain the highest quality patient care services at reasonable prices. In such cases, it would not be in VA's best interest to exclude non-profit teaching hospitals and universities and other similar high quality large businesses from the competition. Small businesses could still compete and would have an equal opportunity to be considered for award. The availability of this authority, while most critical to direct patient care service acquisitions, could be a necessary element of other commercial service acquisitions that are critical to the optimum functioning of the medical centers.

In some limited circumstances, the waiver authority of section 873.107 may have a beneficial impact on small entities. VA has authority to contract on a sole source basis with medical schools, hospitals, and clinics affiliated with VA. Medical schools, hospitals, and clinics are almost exclusively large or nonprofit businesses. Under the FAR, if a VA medical center wishes to seek competition for services currently being acquired from its affiliate, the affiliate would be excluded from bidding on that competition if there were two or more small businesses capable of providing the services. It is in VA's best interest to obtain state-of-the-art medical services from the highest qualified sources at reasonable prices. Without the waiver authority, VA medical centers would most likely continue to award sole source contracts to their affiliates rather than seek competition, since, under a competitive solicitation, those affiliates might be excluded as potential sources for those services due to the current FAR requirement to set acquisitions aside for small business. While VA medical centers might be willing to consider other sources, they generally are unwilling to exclude their affiliates as potential sources. However, under the waiver procedures of the rule, VA medical centers would no longer be required to set an acquisition aside for small business and exclude their affiliates from consideration. Accordingly, VA medical centers may be more likely to issue competitive solicitations for highly technical medical services rather than acquire such services on a sole source basis from their affiliates. Rather than reducing small business access to VA acquisitions of medical services, the waiver process could result in increased access to such acquisitions by small businesses. In this regard, VA intends to monitor, through the Federal Procurement Data System, the use of the procedures provided in this rule and the

impact on VA's socioeconomic programs.

2. The FAR requires that all proposed acquisitions, including sole source acquisitions, exceeding $25,000, with certain exceptions, be transmitted to the GPE. The rule differs from the FAR in several ways. First, it provides, at section 873.108(a), that acquisitions exceeding the simplified acquisition threshold (SAT) (currently $100,000) would not have to be announced in the GPE. Rather, the rule requires that contracting officers publicly announce such proposed acquisitions utilizing a medium designed to obtain competition to the maximum extent practicable. The rule lists a number of examples for where the announcements may be announced, including the GPE. The intent of the rule is to maximize the dissemination of information regarding such proposed acquisitions, not to limit dissemination. Most acquisitions for services are of interest only to the local community. In many cases, it is impossible for a firm located some distance from a VA medical center to provide coronary bypass operations, X-ray or oncology services, or other services necessary to operate the medical center, on a timely basis. We believe that both small and large local service providers of health-care resources (*e.g.,* hospitals and clinics) are more likely to be made aware of acquisition opportunities if the acquisitions are announced in mediums that are seen and read by the local service community or if they are contacted directly. Accordingly, we believe this provision of the rule will tend to increase competition rather than decrease competition and will provide small businesses with increased opportunities.

Second, the rule at section 873.108(b) provides that sole source acquisitions from institutions affiliated with VA and from medical practice groups and other entities associated with an affiliated institution are exempt from the requirement for synopsis in the GPE. 38 U.S.C. 8153 specifically authorizes VA to acquire health-care resources on a sole source basis from institutions affiliated with VA and from medical practice groups and other entities associated with an affiliated institution. Exempting such acquisitions from synopsis in the GPE is consistent with statute, which imposes no requirement for VA to solicit and consider any other offers. Thus, this provision of the rule will have no impact on competition, since competition is not required under any circumstances.

Section 873.108(b) also exempts from publication sole source acquisitions of hospital care, medical services, and other health-care services from any source, whether or not the source is affiliated with VA. However, as required by 38 U.S.C. 8153(a)(3)(D), acquisitions from non-affiliates, if conducted on a sole source basis, must still be justified and approved. Acquisitions for hospital care, medical services, or other health-care services would usually be conducted on a sole source basis only if there was an emergency need for such services. Otherwise, the acquisitions would likely be conducted competitively, if not acquired from an affiliate. The FAR provides an exemption from synopsis in the GPE under conditions of unusual or compelling urgency and where the Government would be seriously injured by any delay due to the publication requirement. We expect that most of the sole source acquisitions of hospital care, medical services, and other health-care services covered by this provision will be conducted under conditions of unusual or compelling urgency. Such acquisitions would include emergency hospital care for a veteran in an area not served by a nearby VA medical center. Even under the FAR, this type of acquisition is exempt from synopsis in the GPE by virtue of its being an urgent and compelling acquisition. This provision of the rule will simplify the acquisition process by freeing the contracting officer from having to make individual determinations regarding publication for each sole source acquisition of hospital care, medical services, and other health-care services. Since we expect most such acquisitions to already be exempt under the FAR, we believe this provision will have little, if any, impact on competition or on awards to small businesses.

Third, the rule at section 873.108(c) exempts acquisitions below the SAT from the requirement for public announcement, including synopsis in the GPE. However, the rule at section 873.104 requires the contracting officer to seek competition to the maximum extent practicable and to permit all responsible sources, as appropriate, to submit a bid, proposal, or quotation. In addition, for acquisitions below the SAT, section 873.111 states that contracting officers should solicit a sufficient number of sources to promote competition to the maximum extent practicable. Section 873.107 requires that acquisitions be set aside for small business. These provisions tend to mitigate any negative impact that section 873.108(c) may have on small businesses.

The alternatives to the above provisions regarding public announcements in the GPE that were considered were to eliminate these provisions and follow the provisions of the FAR or to limit the exemptions to specific categories of acquisitions, such as acquisitions for medical services. The objectives of the rule are to allow VA to become more efficient in procuring health-care resources. The intent of this rule is to provide procurement processes that are simpler and less time consuming than those of the FAR. As discussed above, we believe that the flexibility to select the public medium that best captures the awareness of interested sources will enable the Department to maximize the effective distribution of information on VA solicitations and more efficiently take advantage of competition without decreasing competition. For this reason, the provisions regarding publicizing contract actions have been retained without change.

List of Subjects

48 CFR Parts 801 and 852

Government Procurement, Reporting and recordkeeping requirements.

48 CFR Parts 806, 812, 837, and 873

Government Procurement.

Approved: October 11, 2002.

Anthony J. Principi,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 48 CFR chapter 8 is amended as follows:

PART 801—VETERANS AFFAIRS ACQUISITION REGULATIONS SYSTEM

1. The authority citation for part 801 continues to read as follows:

Authority: 38 U.S.C. 501 and 40 U.S.C. 486(c).

801.301–70 [Amended]

2. The chart in section 801.301–70, paragraph (c) is amended by adding two OMB information collection approval numbers to read as follows:

801.301–70 Paperwork Reduction Act requirements.

* * * * *

48 CFR part or section where identified and described	Current OMB control No.
* * * * *	
852.207–70	2900–0590
* * * * *	
852.237–7	2900–0590
* * * * *	

801.602–70 [Amended]

3. In 801.602–70, paragraphs (a)(4)(vi) and (a)(4)(vii) are revised to read as follows:

801.602–70 Legal/technical review requirements to be met prior to contract execution.

(a) * * *

(4) * * *

(vi) Competitive contracts exceeding $1.5 million and noncompetitive contracts exceeding $500,000 for the acquisition of scarce medical specialist services acquired under the authority of 38 U.S.C. 7409.

(vii) Competitive contracts exceeding $1.5 million and noncompetitive contracts exceeding $500,000 for the acquisition of health-care resources acquired under the authority of 38 U.S.C. 8151–8153.

* * * * *

801.602–71 [Amended]

4. In 801.602–71, paragraph (b)(2) is revised to read as follows:

801.602–71 Processing contracts for legal/technical review.

* * * * *

(b) * * *

(2) Proposed contracts and agreements for scarce medical specialist services or for the mutual use or exchange of use of health-care resources, as specified in 801.602–70(a)(4)(vi) and (a)(4)(vii), will be forwarded to Central Office in accordance with Veterans Health Administration directives and VA Manual M–1, Part 1, Chapter 34, for review and submission to the Office of the General Counsel (025).

* * * * *

801.602–72 [Amended]

5. In 801.602–72, paragraph (b) is revised to read as follows:

801.602–72 Documents to be submitted for legal review.

* * * * *

(b) For proposed contracts and agreements for scarce medical specialist services or for the mutual use or exchange of use of health-care resources, as specified in 801.602–70(a)(4)(vi) and (a)(4)(vii), the documents referred to in VA Manual M–1, Part 1, Chapter 34.

* * * * *

PART 806—COMPETITION REQUIREMENTS

6. The authority citation for part 806 continues to read as follows:

Authority: 38 U.S.C. 501 and 40 U.S.C. 486(c).

7. Section 806.302–5 is amended by:

a. Revising paragraph (b).

b. Redesignating paragraph (c) as paragraph (d).

c. Adding a new paragraph (c).

The revision and addition read as follows:

806.302–5 Authorized or required by statute.

* * * * *

(b) Contracts or agreements for the mutual use or exchange of use of health-care resources, consisting of commercial services, the use of medical equipment or space, or research, negotiated under the authority of 38 U.S.C. 8151–8153, are approved for other than full and open competition only when such contracts or agreements are with institutions affiliated with the Department of Veterans Affairs, pursuant to 38 U.S.C. 7302, with medical practice groups or other approved entities associated with affiliated institutions (entities will be approved if determined legally to be associated with affiliated institutions), or with blood banks, organ banks, or research centers. The justification and approval requirements of FAR 6.303 and VAAR 806.304 do not apply to such contracts or agreements.

(c) Contracts or agreements for the mutual use or exchange of use of health-care resources, consisting of commercial services or the use of medical equipment or space, negotiated under the authority of 38 U.S.C. 8151–8153, and not acquired under the authority of paragraph (b) of this section, may be conducted without regard to any law or regulation that would otherwise require the use of competitive procedures for procuring resources, provided the procurement is conducted in accordance with the simplified procedures contained in (VAAR) 48 CFR part 873. The justification and approval requirements of FAR 6.303 and 806.304 shall apply to such contracts or agreements conducted on a sole source basis.

* * * * *

PART 812—ACQUISITION OF COMMERCIAL ITEMS

8. The authority citation for part 812 continues to read as follows:

Authority: 38 U.S.C. 501 and 40 U.S.C. 486(c).

9. In 812.301, paragraph (c) is revised and paragraph (g) is added to read as follows:

812.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(c) The provisions and clauses in the following VAAR sections must be used, when appropriate, in accordance with the prescriptions contained therein or elsewhere in the VAAR, in requests for quotations, solicitations, or contracts for the acquisition of commercial items:

(1) 852.207–70, Report of employment under commercial activities.

(2) 852.211–71, Guarantee clause.

(3) 852.211–72, Inspection.

(4) 852.211–73, Frozen processed foods.

(5) 852.211–74, Telecommunications equipment.

(6) 852.211–75, Technical industry standards.

(7) 852.214–70, Caution to bidders-bid envelopes.

(8) 852.216–70, Estimated quantities for requirements contracts.

(9) 852.229–70, Purchases from patient's funds.

(10) 852.229–71, Purchases for patients using Government funds and/or personal funds of patients.

(11) 852.233–70, Protest content.

(12) 852.237–7, Indemnification and Medical Liability Insurance.

(13) 852.237–70, Contractor responsibilities.

(14) 852.237–71, Indemnification and insurance (vehicle and aircraft service contracts).

(15) 852.252–1, Provisions or clauses requiring completion by the offeror or prospective contractor.

(16) 852.270–1, Representatives of contracting officers.

(17) 852.270–2, Bread and bakery products.

(18) 852.270–3, Purchase of shellfish.

* * * * *

(g) When soliciting for commercial services or the use of medical equipment or space under the authority of part 873 and 38 U.S.C. 8151–8153, the provisions and clauses in the following VAAR sections may be used in accordance with the prescriptions contained therein or elsewhere in the VAAR:

(1) 852.273–70, Late offers.

(2) 852.273–71, Alternative negotiation techniques.

(3) 852.273–72, Alternative evaluation.

(4) 852.273–73, Evaluation—health-care resources.

(5) 852.273–74, Award without exchanges.

PART 837—SERVICE CONTRACTING

10. The authority citation for part 837 continues to read as follows:

Authority: 38 U.S.C. 501 and 40 U.S.C. 486(c).

11. Section 837.403 is amended by revising the first sentence of the paragraph to read as follows:

837.403 Contract clause.

The contracting officer shall insert the clause at 852.237–7, Indemnification and Medical Liability Insurance, in lieu of FAR Clause 52.237–7, in solicitations and contracts for nonpersonal health-care services, including solicitations and contracts for nonpersonal health-care services awarded under the authority of 38 U.S.C. 8151–8153 and (VAAR) 48 CFR part 873. * * *

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

12. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 501 and 40 U.S.C. 486(c).

13. In section 852.207–70, the introductory text is revised to read as follows:

852.207–70 Report of employment under commercial activities.

As prescribed in 807.304–77 and 873.110, the following clause must be included in A–76 cost comparison solicitations and solicitations issued under the authority of 38 U.S.C. 8151–8153 which may result in the conversion, from in-house to contract performance, of work currently being performed by VA employees:

* * * * *

14. Section 852.273–70 is added to read as follows:

852.273–70 Late offers.

As prescribed in 873.110(a), insert the following provision:

Late Offers (Jan 2003)

This provision replaces paragraph (f) of FAR provision 52.212–1. Offers or modifications of offers received after the time set forth in a request for quotations or request for proposals may be considered, at the discretion of the contracting officer, if determined to be in the best interest of the Government. Late bids submitted in response to an invitation for bid (IFB) will not be considered.

(End of provision)

15. Section 852.273–71 is added to read as follows:

852.273–71 Alternative negotiation techniques.

As prescribed in 873.110(b), insert the following provision:

Alternative Negotiation Techniques (Jan 2003)

The contracting officer may elect to use the alternative negotiation techniques described in section 873.111(e) of 48 Code of Federal Regulations Chapter 8 in conducting this procurement. If used, offerors may respond by maintaining offers as originally submitted, revising offers, or submitting an alternative offer. The Government may consider initial offers unless revised or withdrawn, revised offers, and alternative offers in making the award. Revising an offer does not guarantee an offeror an award.

(End of provision)

16. Section 852.273–72 is added to read as follows:

852.273–72 Alternative evaluation.

As prescribed in 873.110(c), insert the following provision:

Alternative Evaluation (Jan 2003)

(a) The Government will award a contract resulting from this solicitation to the responsible offeror submitting the lowest priced offer that conforms to the solicitation. During the specified period for receipt of offers, the amount of the lowest offer will be posted and may be viewed by—[*Contracting officer insert description of how the information may be viewed electronically or otherwise*]—. Offerors may revise offers anytime during the specified period. At the end of the specified time period for receipt of offers, the responsible offeror submitting the lowest priced offer will be in line for award.

(b) Except when it is determined not to be in the Government's best interest, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are materially unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(End of provision)

17. Section 852.273–73 is added to read as follows:

852.273–73 Evaluation—health-care resources.

As prescribed in 873.110(d), in lieu of FAR provision 52.212–2, the contracting officer may insert a provision substantially as follows:

Evaluation—Health-Care Resources (January 2003)

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer, conforming to the solicitation, will be most advantageous to the Government, price and other factors considered. The following information or factors shall be used to evaluate offers:

—[*Contracting officer insert evaluation information or factors, such as technical capability to meet the Government's requirements, past performance, or such other evaluation information or factors as the contracting officer deems necessary to evaluate offers. Price must be evaluated in every acquisition. The contracting officer may include the evaluation information or factors in their relative order of importance, such as in descending order of importance. The relative importance of any evaluation information must be stated in the solicitation.*]—

(b) Except when it is determined not to be in the Government's best interest, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are materially unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(c) If this solicitation is a request for proposals (RFP), a written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of provision)

18. Section 852.273–74 is added to read as follows:

852.273–74 Award without exchanges.

As prescribed in 873.110(e), insert the following provision:

Award Without Exchanges (Jan 2003)

The Government intends to evaluate proposals and award a contract without exchanges with offerors. Therefore, each initial offer should contain the offeror's best terms from a cost or price and technical standpoint. However, the Government reserves the right to conduct exchanges if later determined by the contracting officer to be necessary.

(End of provision)

19. Part 873 is added to read as follows:

PART 873—SIMPLIFIED ACQUISITION PROCEDURES FOR HEALTH-CARE RESOURCES

Sec.

873.101 Policy.
873.102 Definitions.
873.103 Priority sources.
873.104 Competition requirements.
873.105 Acquisition planning.
873.106 Presolicitation exchanges with industry.
873.107 Socioeconomic programs.
873.108 Publicizing contract actions.
873.109 General requirements for acquisition of health-care resources.

873.110 Solicitation provisions.
873.111 Acquisition strategies for health-care resources.
873.112 Evaluation information.
873.113 Exchanges with offerors.
873.114 Best value pool.
873.115 Proposal revisions.
873.116 Source selection decision.
873.117 Award to successful offeror.
873.118 Debriefings.

Authority: 38 U.S.C. 8151–8153.

873.101 Policy.

The simplified acquisition procedures set forth in this Department of Veterans Affairs Acquisition Regulation (VAAR) part apply to the acquisition of health-care resources consisting of commercial services or the use of medical equipment or space. These procedures shall be used in conjunction with the Federal Acquisition Regulation (FAR) and other parts of VAAR. However, when a policy or procedure in FAR or another part of VAAR differs from the procedures contained in this part, this part shall take precedence. These procedures contain more flexibility than provided in FAR or elsewhere in VAAR.

873.102 Definitions.

Commercial service means a service, except construction exceeding $2,000 and architect-engineer services, that is offered and sold competitively in the commercial marketplace, is performed under standard commercial terms and conditions, and is procured using firm-fixed price contracts.

Health-care providers includes health-care plans and insurers and any organizations, institutions, or other entities or individuals who furnish health-care resources.

Health-care resource includes hospital care and medical services (as those terms are defined in section 1701 of title 38 United States Code (U.S.C.), any other health-care service, and any health-care support or administrative resource, including the use of medical equipment or space.

873.103 Priority sources.

Without regard to FAR 8.001(a)(2), except for the acquisition of services available from the Committee for Purchase From People Who Are Blind or Severely Disabled, pursuant to the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) and FAR subpart 8.7, there are no priority sources for the acquisition of health-care resources consisting of commercial services or the use of medical equipment or space.

873.104 Competition requirements.

(a) Without regard to FAR part 6, if the health-care resource required is a commercial service, the use of medical equipment or space, or research, and is to be acquired from an institution affiliated with the Department in accordance with section 7302 of title 38 U.S.C., including medical practice groups and other approved entities associated with affiliated institutions (entities will be approved if determined legally to be associated with affiliated institutions), or from blood banks, organ banks, or research centers, the resource may be acquired on a sole source basis.

(b) Acquisition of health-care resources identified in paragraph (a) of this section are not required to be publicized as otherwise required by 873.108 or FAR 5.101. In addition, written justification, as otherwise set forth in section 303(f) of the Federal Property and Administration Services Act of 1949 (41 U.S.C. 253(f)) and FAR part 6, is not required.

(c) Without regard to FAR 6.101, if the health-care resource required is a commercial service or the use of medical equipment or space, and is to be acquired from an entity not described in paragraph (a) of this section, contracting officers must seek competition to the maximum extent practicable and must permit all responsible sources, as appropriate under the provisions of this part, to submit a bid, proposal or quotation (as appropriate) for the resources to be procured and provide for the consideration by the Department of bids, proposals, or quotations so submitted.

(d) Without regard to FAR 5.101, acquisition of health-care resources identified in paragraph (c) of this section shall be publicized as otherwise required by 873.108. Moreover, for any such acquisition described in paragraph (c) of this section to be conducted on a sole source basis, the contracting officer must prepare a justification that includes the information and is approved at the levels prescribed in section 303(f) of the Federal Property and Administration Services Act of 1949 (41 U.S.C. 253(f)) and FAR part 6.

873.105 Acquisition planning.

(a) Acquisition planning is an indispensable component of the total acquisition process.

(b) For the acquisition of health-care resources consisting of commercial services or the use of medical equipment or space, where the acquisition is expected to exceed the simplified acquisition threshold (SAT), an acquisition team must be assembled. The team shall be tailored by the contracting officer for each particular acquisition expected to exceed the SAT. The team should consist of a mix of staff, appropriate to the complexity of the acquisition, and may include contracting, fiscal, legal, administrative, and technical personnel, and such other expertise as necessary to assure a comprehensive acquisition plan. The team should include the small business advocate representing the contracting activity or a higher level designee and the SBA Procurement Center Representative (PRC), if available. As a minimum, the team must include the contracting officer and a representative of the requesting service.

(c) Prior to determining whether a requirement is suitable for acquisition using these simplified acquisition procedures, the contracting officer or the acquisition team, as appropriate, must conduct market research to identify interested businesses. It is the responsibility of the contracting officer to ensure the requirement is appropriately publicized and information about the procurement opportunity is adequately disseminated as set forth in 873.108.

(d) In lieu of the requirements of FAR part 7 addressing documentation of the acquisition plan, the contracting officer may conduct an acquisition strategy meeting with cognizant offices to seek approval for the proposed acquisition approach. If a meeting is conducted, briefing materials shall be presented to address the acquisition plan topics and structure in FAR 7.105. Formal written minutes shall be prepared to summarize decisions, actions, and conclusions and included in the contract file, along with a copy of the briefing materials.

873.106 Presolicitation exchanges with industry.

(a) This section shall be used in lieu of FAR part 10, except as provided in paragraph (b)(3)of this section. In conducting market research, exchange of information by all interested parties involved in an acquisition, from the earliest identification of a requirement through release of the solicitation, is encouraged. Interested parties include potential offerors, end users, Government acquisition and support personnel, and others involved in the conduct or outcome of the acquisition. The nature and extent of presolicitation exchanges between the Government and industry shall be a matter of the contracting officer's discretion (for acquisitions not exceeding the simplified acquisition threshold) or the acquisition team's discretion, as coordinated by the contracting officer.

(b) Techniques to promote early exchange of information include—

(1) Industry or small business conferences;

(2) Public hearings;
(3) Market research in accordance with FAR 10.002(b), which shall be followed to the extent that the provisions therein would provide relevant information;
(4) One-on-one meetings with potential offerors;
(5) Presolicitation notices;
(6) Draft Requests for proposals (RFPs);
(7) Requests for information (RFIs);
(8) Presolicitation or preproposal conferences;
(9) Site visits;
(10) Electronic notices (*e.g.*, Internet); and
(11) Use of the Procurement Marketing and Access Network (PRO–NET).

873.107 Socioeconomic programs.

(a) *Implementation.* This section provides additional authority, over and above that found at FAR 19.502, to waive small business set-asides. For acquisitions above the micro-purchase threshold, if, through market research, the contracting officer determines that there is reasonable expectation that reasonably priced bids, proposals, or quotations will be received from two or more responsible small businesses, a requirement for health-care resources must be reserved for small business participation. Without regard to FAR 13.003(b)(1), 19.502–2, and 19.502–3, the head of the contracting activity (HCA) may approve a waiver from the requirement for any set-aside for small business participation when a waiver is determined to be in the best interest of the Government.

(b) *Rejecting Small Business Administration (SBA) recommendations.* (1) The contracting officer (or, if a waiver has been approved in accordance with paragraph (a) of this section, the HCA) must consider and respond to a recommendation from an SBA representative to set a procurement aside for small business within 5 working days. If the recommendation is rejected by the contracting officer (or, if a waiver has been approved, by the HCA) and if SBA intends to appeal that determination, SBA must, within 2 working days after receipt of the determination, notify the contracting officer involved of SBA's intention to appeal.

(2) Upon receipt of the notification of SBA's intention to appeal and pending issuance of a final Department appeal decision to SBA, the contracting officer involved must suspend action on the acquisition unless a determination is made in writing by the contracting officer that proceeding to contract award and performance is in the public interest. The contracting officer must promptly notify SBA of the determination to proceed with the solicitation and/or contract award and must provide a copy of the written determination to SBA.

(3) SBA shall be allowed 10 working days after receiving the rejection notice from the contracting officer (or the HCA, if a waiver has been approved) for acquisitions not exceeding $5 million, or 15 working days after receiving the rejection notice for acquisitions exceeding $5 million, to file an appeal. SBA must notify the contracting officer within this 10 or 15 day period whether an appeal has, in fact, been taken. If notification is not received by the contracting officer within the applicable period, it shall be deemed that an appeal was not taken.

(4) SBA shall submit appeals to the Secretary. Decisions shall be made by the Procurement Executive, whose decisions shall be final.

(c) *Contracting with the Small Business Administration (the 8(a) Program).* The procedures of FAR 19.8 shall be followed where a responsible 8(a) contractor has been identified.

(d) *Certificates of Competency and determinations of responsibility.* The Director, Office of Small and Disadvantaged Business Utilization (OSDBU), Department of Veterans Affairs (VA), and the Assistant Administrator, Office of Industrial Assistance, Small Business Administration (SBA), shall serve as ombudsmen to assist VA contracting officers on any issues relating to Certificates of Competency (COC). Copies of all COC referrals to SBA shall be submitted to the Director, OSDBU (00SB).

873.108 Publicizing contract actions.

(a) Without regard to FAR 5.101, all acquisitions under this part 873, except as provided in paragraph (b) of this section, for dollar amounts in excess of the simplified acquisition threshold (SAT), as set forth in FAR part 13, shall be publicly announced utilizing a medium designed to obtain competition to the maximum extent practicable and to permit all responsible sources, as appropriate under the provisions of this part, to submit a bid, proposal, or quotation (as appropriate).

(1) The publication medium may include the Internet, including the Governmentwide point of entry (GPE), and local, regional or national publications or journals, as appropriate, at the discretion of the contracting officer, depending on the complexity of the acquisition.

(2) Without regard to FAR 5.203, notice shall be published for a reasonable time prior to issuance of a request for quotations (RFQ) or a solicitation, depending on the complexity or urgency of the acquisition, in order to afford potential offerors a reasonable opportunity to respond. If the notice includes a complete copy of the RFQ or solicitation, a prior notice is not required, and the RFQ or solicitation shall be considered to be announced and issued at the same time.

(3) The notice may include contractor qualification parameters, such as time for delivery of service, credentialing or medical certification requirements, small business or other socio-economic preferences, the appropriate small business size standard, and such other qualifications as the contracting officer deems necessary to meet the needs of the Government.

(b) The requirement for public announcement does not apply to sole source acquisitions, described in 873.104(a), from institutions affiliated with the Department in accordance with section 7302 of title 38 U.S.C., including medical practice groups and other approved entities associated with affiliated institutions (entities will be approved if determined legally to be associated with affiliated institutions), or from blood banks, organ banks, or research centers. In addition, the requirement for public announcement does not apply to sole source acquisitions of hospital care and medical services (as those terms are defined in section 1701 of title 38 U.S.C.) or any other health-care services, including acquisitions for the mutual use or exchange of use of such services. However, as required by 38 U.S.C. 8153(a)(3)(D), acquisitions from non-affiliates, if conducted on a sole source basis, must still be justified and approved (see 873.104(d)).

(c) For acquisitions below the SAT, a public announcement is optional.

(d) Each solicitation issued under these procedures must prominently identify that the requirement is being solicited under the authority of 38 U.S.C. 8153 and part 873.

873.109 General requirements for acquisition of health-care resources.

(a) *Source selection authority.* Contracting officers shall be the source selection authority for acquisitions of health-care resources, consisting of commercial services or the use of medical equipment or space, utilizing the guidance contained in this part 873.

(b) *Statement of work/Specifications.* Statements of work or specifications must define the requirement and should, in most instances, include qualifications or limitations such as time limits for delivery of service, medical certification or credentialing restrictions, and small business or other socio-economic preferences. The contracting officer may include any other such terms as the contracting officer deems appropriate for each specific acquisition.

(c) *Documentation.* Without regard to FAR 13.106–3(b), 13.501(b), or 15.406–3, the contract file must include:

(1) A brief written description of the procedures used in awarding the contract;

(2) The market research, including the determination that the acquisition involves health-care resources;

(3) The number of offers received; and

(4) An explanation, tailored to the size and complexity of the acquisition, of the basis for the contract award decision.

(d) *Time for receipt of quotations or offers.* (1) Without regard to FAR 5.203, contracting officers shall set a reasonable time for receipt of quotations or proposals in requests for quotations (RFQs) and solicitations.

(2) Without regard to FAR 15.208 or 52.212–1(f), quotations or proposals received after the time set forth in an RFQ or request for proposals (RFP) may be considered at the discretion of the contracting officer if determined to be in the best interest of the Government. Contracting officers must document the rationale for accepting quotations or proposals received after the time specified in the RFQ or RFP. This paragraph (d)(2) shall not apply to RFQs or RFPs if alternative evaluation techniques described in 873.111(e)(1)(ii) are used. This paragraph (d)(2) does not apply to invitations for bid (IFBs).

(e) *Cancellation of procurements.* Without regard to FAR 14.404–1, any acquisition may be canceled by the contracting officer at any time during the acquisition process if cancellation is determined to be in the best interest of the Government.

873.110 Solicitation provisions.

(a) As provided in 873.109(d), contracting officers shall insert the provision at 852.273–70, Late offers, in all requests for quotations (RFQs) and requests for proposals (RFPs) exceeding the micro-purchase threshold.

(b) The contracting officer shall insert a provision in RFQs and solicitations, substantially the same as the provision at 852.273–71, Alternative negotiation techniques, when either of the alternative negotiation techniques described in 873.111(e)(1) will be used.

(c) The contracting officer shall insert the provision at 852.273–72, Alternative evaluation, in lieu of the provision at 52.212–2, Evaluation—Commercial Items, when the alternative negotiation technique described in 873.111(e)(1)(ii) will be used.

(d) When evaluation information, as described in 873.112, is to be used to select a contractor under an RFQ or RFP for health-care resources consisting of commercial services or the use of medical equipment or space, the contracting officer may insert the provision at 852.273–73, Evaluation—health-care resources, in the RFQ or RFP in lieu of FAR provision 52.212–2.

(e) As provided at 873.113(f), if award may be made without exchange with vendors, the contracting officer shall include the provision at 852.273–74, Award without exchanges, in the RFQ or RFP.

(f) The contracting officer shall insert the clauses at FAR 52.207–3, Right of First Refusal of Employment, and at 852.207–70, Report of employment under commercial activities, in all RFQs, solicitations, and contracts issued under the authority of 38 U.S.C. 8151–8153 which may result in a conversion, from in-house performance to contract performance, of work currently being performed by Department of Veterans Affairs employees.

873.111 Acquisition strategies for health-care resources.

Without regard to FAR 13.003 or 13.500(a), the following acquisition processes and techniques may be used, singly or in combination with others, as appropriate, to design acquisition strategies suitable for the complexity of the requirement and the amount of resources available to conduct the acquisition. These strategies should be considered during acquisition planning. The contracting officer shall select the process most appropriate to the particular acquisition. There is no preference for sealed bid acquisitions.

(a) *Request for quotations.* (1) Without regard to FAR 6.1 or 6.2, contracting officers must solicit a sufficient number of sources to promote competition to the maximum extent practicable and to ensure that the purchase is advantageous to the Government, based, as appropriate, on either price alone or price and other factors (*e.g.*, past performance and quality). RFQs must notify vendors of the basis upon which the award is to be made.

(2) For acquisitions in excess of the SAT, the procedures set forth in FAR part 13 concerning RFQs may be utilized without regard to the dollar thresholds contained therein.

(b) *Sealed bidding.* FAR part 14 provides procedures for sealed bidding.

(c) *Negotiated acquisitions.* The procedures of FAR parts 12, 13, and 15 shall be used for negotiated acquisitions, except as modified in this part.

(d) *Multiphase acquisition technique.* (1) *General.* Without regard to FAR 15.202, multiphase acquisitions may be appropriate when the submission of full proposals at the beginning of an acquisition would be burdensome for offerors to prepare and for Government personnel to evaluate. Using multiphase techniques, the Government may seek limited information initially, make one or more down-selects, and request a full proposal from an individual offeror or limited number of offerors. Provided that the notice notifies offerors, the contracting officer may limit the number of proposals during any phase to the number that will permit an efficient competition among proposals offering the greatest likelihood of award. The contracting officer may indicate in the notice an estimate of the greatest number of proposals that will be included in the down-select phase. The contracting officer may down-select to a single offeror.

(2) *First phase notice.* In the first phase, the Government shall publish a notice (see 873.108) that solicits responses and that may provide, as appropriate, a general description of the scope or purpose of the acquisition and the criteria that will be used to make the initial down-select decision. The notice may also inform offerors of the evaluation criteria or process that will be used in subsequent down-select decisions. The notice must contain sufficient information to allow potential offerors to make an informed decision about whether to participate in the acquisition. The notice must advise offerors that failure to participate in the first phase will make them ineligible to participate in subsequent phases. The notice may be in the form of a synopsis in the Governmentwide point of entry (GPE) or a narrative letter or other appropriate method that contains the information required by this paragraph.

(3) *First phase responses.* Offerors shall submit the information requested in the notice described in paragraph (d)(2) of this section. Information sought in the first phase may be limited to a statement of qualifications and other appropriate information (*e.g.*, proposed technical concept, past performance information, limited pricing information).

(4) *First phase evaluation and down-select.* The Government shall evaluate all offerors' submissions in accordance with the notice and make a down-select decision.

(5) *Subsequent phases.* Additional information shall be sought in the second phase so that a down-select can be performed or an award made without exchanges, if necessary. The contracting officer may conduct exchanges with remaining offeror(s), request proposal revisions, or request best and final offers, as determined necessary by the contracting officer, in order to make an award decision.

(6) *Debriefing.* Without regard to FAR 15.505, contracting officers must debrief offerors as required by 873.118 when they have been excluded from the competition.

(e) *Alternative negotiation techniques.* (1) Contracting officers may utilize alternative negotiation techniques for the acquisition of health-care resources. Alternative negotiation techniques may be used when award will be based on either price or price and other factors. Alternative negotiation techniques include but are not limited to:

(i) Indicating to offerors a price, contract term or condition, commercially available feature, and/or requirement (beyond any requirement or target specified in the solicitation) that offerors will have to improve upon or meet, as appropriate, in order to remain competitive.

(ii) Posting offered prices electronically or otherwise (without disclosing the identity of the offerors) and permitting revisions of offers based on this information.

(2) Except as otherwise permitted by law, contracting officers shall not conduct acquisitions under this section in a manner that reveals the identities of offerors, releases proprietary information, or otherwise gives any offeror a competitive advantage (see FAR 3.104).

873.112 Evaluation information.

(a) Without regard to FAR 15.304 (except for 15.304(c)(1) and (c)(3), which do apply to acquisitions under this authority), the criteria, factors, or other evaluation information that apply to an acquisition, and their relative importance, are within the broad discretion of agency acquisition officials as long as the evaluation information is determined to be in the best interest of the Government.

(b) Price or cost to the Government must be evaluated in every source selection. Past performance shall be evaluated in source selections for negotiated competitive acquisitions exceeding the SAT unless the contracting officer documents that past performance is not an appropriate evaluation factor for the acquisition.

(c) The quality of the product or service may be addressed in source selection through consideration of information such as past compliance with solicitation requirements, technical excellence, management capability, personnel qualifications, and prior experience. The information required from quoters, bidders, or offerors shall be included in notices or solicitations, as appropriate.

(d) The relative importance of any evaluation information included in a solicitation must be set forth therein.

873.113 Exchanges with offerors.

(a) Without regard to FAR 15.201 or 15.306, negotiated acquisitions generally involve exchanges between the Government and competing offerors. Open exchanges support the goal of efficiency in Government by providing the Government with relevant information (in addition to that submitted in the offeror's initial proposal) needed to understand and evaluate the offeror's proposal. The nature and extent of exchanges between the Government and offerors is a matter of contracting officer judgment. Clarifications, communications, and discussions, as provided for in the FAR, are concepts not applicable to acquisitions under this part 873.

(b) Exchanges with potential offerors may take place throughout the source selection process. Exchanges may start in the planning stages and continue through contract award. Exchanges should occur most often with offerors determined to be in the best value pool (see 873.114). The purpose of exchanges is to ensure there is mutual understanding between the Government and the offerors on all aspects of the acquisition, including offerors' submittals/proposals. Information disclosed as a result of oral or written exchanges with an offeror may be considered in the evaluation of an offeror's proposal.

(c) Exchanges may be conducted, in part, to obtain information that explains or resolves ambiguities or other concerns (*e.g.*, perceived errors, perceived omissions, or perceived deficiencies) in an offeror's proposal.

(d) Exchanges shall only be initiated if authorized by the contracting officer and need not be conducted with all offerors.

(e) *Improper exchanges.* Except for acquisitions based on alternative negotiation techniques contained in 873.111(e)(1), the contracting officer and other Government personnel involved in the acquisition shall not disclose information regarding one offeror's proposal to other offerors without consent of the offeror in accordance with FAR parts 3 and 24.

(f) Award may be made on initial proposals without exchanges if the solicitation states that the Government intends to evaluate proposals and make award without exchanges, unless the contracting officer determines that exchanges are considered necessary.

873.114 Best value pool.

(a) Without regard to FAR 15.306(c), the contracting officer may determine the most highly rated proposals having the greatest likelihood of award based on the information or factors and subfactors in the solicitation. These vendors constitute the best value pool. This determination is within the sole discretion of the contracting officer. Competitive range determinations, as provided for in the FAR, are not applicable to acquisitions under this part 873.

(b) In planning an acquisition, the contracting officer may determine that the number of proposals that would otherwise be included in the best value pool is expected to exceed the number at which an efficient, timely, and economical competition can be conducted. In reaching such a conclusion, the contracting officer may consider such factors as the results of market research, historical data from previous acquisitions for similar services, and the resources available to conduct the source selection. Provided the solicitation notifies offerors that the best value pool can be limited for purposes of making an efficient, timely, and economical award, the contracting officer may limit the number of proposals in the best value pool to the greatest number that will permit an efficient competition among the proposals offering the greatest likelihood of award. The contracting officer may indicate in the solicitation the estimate of the greatest number of proposals that will be included in the best value pool. The contracting officer may limit the best value pool to a single offeror.

(c) If the contracting officer determines that an offeror's proposal is no longer in the best value pool, the proposal shall no longer be considered for award. Written notice of this decision must be provided to unsuccessful offerors at the earliest practicable time.

873.115 Proposal revisions.

(a) Without regard to FAR 15.307, the contracting officer may request proposal revisions as often as needed during the proposal evaluation process at any time prior to award from vendors remaining in the best value pool. Proposal revisions shall be submitted in writing. The contracting officer may establish a common cutoff date for receipt of proposal revisions. Contracting officers may request best and final offers. In any case, contracting officers and acquisition team members must safeguard proposals, and revisions thereto, to avoid unfair dissemination of an offeror's proposal.

(b) If an offeror initially included in the best value pool is no longer considered to be among those most likely to receive award after submission of proposal revisions and subsequent evaluation thereof, the offeror may be eliminated from the best value pool without being afforded an opportunity to submit further proposal revisions.

(c) Requesting and/or receiving proposal revisions do not necessarily conclude exchanges. However, requests for proposal revisions should advise offerors that the Government may make award without obtaining further revisions.

873.116 Source selection decision.

(a) An integrated comparative assessment of proposals should be performed before source selection is made. The contracting officer shall independently determine which proposal(s) represents the best value, consistent with the evaluation information or factors and subfactors in the solicitation, and that the prices are fair and reasonable. The contracting officer may determine that all proposals should be rejected if it is in the best interest of the Government.

(b) The source selection team, or advisory boards or panels, may conduct comparative analysis(es) of proposals and make award recommendations, if the contracting officer requests such assistance.

(c) The source selection decision must be documented in accordance with FAR 15.308.

873.117 Award to successful offeror.

(a) The contracting officer shall award a contract to the successful offeror by furnishing the contract or other notice of the award to that offeror.

(b) If a request for proposal (RFP) process was used for the solicitation and if award is to be made without exchanges, the contracting officer may award a contract without obtaining the offeror's signature a second time. The offeror's signature on the offer constitutes the offeror's agreement to be bound by the offer. If a request for quotation (RFQ) process was used for the solicitation, and if the contracting officer determines there is a need to establish a binding contract prior to commencement of work, the contracting officer should obtain the offeror's acceptance signature on the contract to ensure formation of a binding contract.

(c) If the award document includes information that is different than the latest signed offer, both the offeror and the contracting officer must sign the contract award.

(d) When an award is made to an offeror for less than all of the items that may be awarded and additional items are being withheld for subsequent award, each notice shall state that the Government may make subsequent awards on those additional items within the offer acceptance period.

873.118 Debriefings.

Offerors excluded from a request for proposals (RFP) may submit a written request for a debriefing to the contracting officer. Without regard to FAR 15.505, preaward debriefings may be conducted by the contracting officer when determined to be in the best interest of the Government. Post-award debriefings shall be conducted in accordance with FAR 15.506.

[FR Doc. 03–1578 Filed 1–23–03; 8:45 am]

BILLING CODE 8320–01–P

Proposed Rules

Federal Register
Vol. 68, No. 16
Friday, January 24, 2003

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–ANE–05–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT8D Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to supersede an existing airworthiness directive (AD), that is applicable to Pratt & Whitney JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines. That AD currently requires a determination of the utilization rate and protective coating type of the 7th, 8th, 9th, 10th, 11th, and 12th stage high pressure compressor (HPC) disks, and removal, inspection for corrosion, and recoating of those HPC disks based on utilization rate. This proposal would require removal and replacement of protective coating of 7th, 8th, 9th, 10th, 11th, and 12th stage HPC disks, initial and repetitive inspections for corrosion pits and cracks, and removal from service as required. This proposal is prompted by operator reports of cracks found on several JT8D steel HPC disks since the existing AD was published. The actions specified in the proposed AD are intended to prevent fracture of the HPC disks, which can result in uncontained release of engine fragments, inflight engine shutdown, and airframe damage.

DATES: Comments must be received by March 25, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–ANE–05–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location, by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: ''*9-ane-adcomment@faa.gov*''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–6600, fax (860) 565–4503. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–ANE–05–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 97–ANE–05–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

On May 29, 1998, the FAA issued AD 98–12–07, Amendment 39–10563 (63 FR 31340, June 9, 1998), to supersede AD 94–20–01, Amendment 39–9020 (59 FR 49175, September 27, 1994). AD 98–12–07 requires a determination of the utilization rate and protective coating type of the 7th, 8th, 9th, 10th, 11th, and 12th stage HPC disks, and removal, inspection for corrosion, and recoating of those HPC disks based on utilization rate, and shortens the inspection interval for certain low utilization disks. That action was prompted by a report of an additional uncontained 9th stage HPC disk failure due to corrosion pitting. That condition, if not corrected, could result in uncontained release of engine fragments, inflight engine shutdown, and airframe damage.

Since that AD was issued, operators have found cracks on various JT8D steel HPC disks. Some of these cracks originate in the tierod hole area of the disk. The inspection intervals in AD 98–12–07 do not account for risk of fractures originating from tierod hole areas. This proposal is a result of a complete re-assessment of the risks associated with a disk fracture due to a corrosion pit. Since the tierod hole corrosion does not correlate well with the utilization rate of the disks, that calculation has been eliminated from the proposal. Also, because the thin-webbed 9th stage disk represents a higher risk of fracture than other part numbers, a tighter inspection interval has been assigned to those parts.

Manufacturer's Service Information

The FAA has reviewed and approved the technical contents of Pratt & Whitney Alert Service Bulletin (ASB) No. A6431, dated November 27, 2002, that describes procedures for initial and repetitive inspections to detect corrosion on HPC disks, and removal

from service of HPC disks corroded beyond serviceable limits. This ASB supersedes ASB No. 6038, referenced in AD 98–12–07.

Differences Between This Proposal and the Manufacturer's Service Information

Although PW ASB No. A6431 dated November 27, 2002, refers to the ASB issuance date for computing compliance intervals, this proposal calls for computing compliance intervals based on the effective date of the AD.

FAA's Determination of an Unsafe Condition and Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other Pratt & Whitney JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines of this same type design, the proposed AD would supersede AD 98–12–07 to require removal and replacement of coating of 7th, 8th, 9th, 10th, 11th, and 12th stage HPC disks, initial and repetitive inspections for corrosion pits and cracks, and removal from service as required. The actions are required to be done in accordance with the alert service bulletin described previously.

Economic Analysis

At the time of publication of AD 98–12–07, there were approximately 11,119 engines of the affected design in the worldwide fleet. The FAA estimated that 6,815 engines installed on aircraft of U.S. registry were affected by AD 94–20–01, and 2 work hours would be necessary to determine the utilization rate and type of surface treatment. Based on domestic fleetwide data, the FAA estimated that approximately 8.7% or 593 engines were considered to have low utilization rates. Approximately 8.6 work hours would be required to remove these engines from the aircraft, 500 work hours to tear down, deblade, and to reassemble the engine, and 8.6 work hours to reinstall the reassembled engines. The FAA estimated 69% of the removed engines would require scrapping the disks. The FAA assumed that 3 disks per engine may require replacement, and the cost of a new disk would be approximately $7,000. The average labor rate is $60 per work hour. Based on these figures, the total cost of AD 94–20–01 on U.S. operators was estimated to be $ 14,279,542. The cost increase between AD 94–20–01 and the superseding AD, AD 98–12–07 was based on the increased inspections of some low utilization disks. The FAA estimated 31% of the low utilization disks required an additional inspection. The cost of these additional inspections was estimated to be $4,426,658. The cost increase between AD 98–12–07 and this proposal is based on the increased domestic fleet size that will be effected by this proposal. The FAA currently estimates the domestic fleet of engines affected by this AD to be 1,800 engines. This is an increase of 1,023 engines or 1.32 times the total number of engines effected by the two previous AD's. The total cost of the previous two AD's was $18,706,200, therefore, the total cost of this AD is $24,692,184, and the cost increase associated with this proposal is $5,985,985.

Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with State authorities prior to publication of this proposed rule.

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–10563, (63 FR 31340 June 9, 1998), and by adding a new airworthiness directive:

Pratt & Whitney: Docket No. 97–ANE–05–AD. Supersedes AD 98–12–07, Amendment 39–10563.

Applicability: This airworthiness directive (AD) is applicable to Pratt & Whitney (PW) JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines. These engines are installed on, but not limited to Boeing 737 and 727 series, and McDonnell Douglas DC–9 series airplanes.

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

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent fracture of the 7th, 8th, 9th, 10th, 11th, and 12th stage high pressure compressor (HPC) disks, which can result in uncontained release of engine fragments, inflight engine shutdown, and airframe damage, do the following:

(a) Perform initial and repetitive inspections of HPC disks for corrosion pits and cracks after stripping the protective coating in accordance with the intervals and procedures specified in the compliance section and accomplishment instructions of PW Alert Service Bulletin (ASB) No. 6431, dated November 27, 2002.

(b) Before further flight, replace HPC disks found with corrosion pits or cracks beyond serviceable limits as defined by PW ASB No. 6431, dated November 27, 2002.

(c) For the purposes of this AD, use the effective date of this AD for computing compliance intervals whenever PW ASB No. A6431, dated November 27, 2002, refers to the issuance date of the ASB.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

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

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197

and 21.199) to operate the airplanes to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on January 16, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–1543 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–126485–01]

RIN 1545–BA06

Statutory Mergers and Consolidations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations; notice of public hearing; and withdrawal of previous notice of proposed rulemaking.

SUMMARY: In the rules and regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to transactions involving corporations engaging in statutory mergers and consolidations. The text of those regulations also serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations. This document also withdraws the notice of proposed rulemaking published in the **Federal Register** at 66 FR 57400 (REG–126485–01) on November 15, 2001.

DATES: Written or electronic comments and outlines of topics to be discussed at the public hearing scheduled for May 21, 2003 at 10 a.m. must be received by April 24, 2003.

ADDRESSES: Send submissions to: CC:ITA:RU (REG–126485–01), Room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044.

Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:ITA:RU (REG–126485–01), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at *http://www.irs.gov/regs.* The public hearing will be held in room 4718 of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Richard M. Heinecke or Reginald Mombrun at (202) 622–7930; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Guy R. Traynor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

On November 15, 2001, the IRS and Treasury published in the **Federal Register** at 66 FR 57400 a notice of proposed rulemaking (REG–126485–01) under section 368(a)(1)(A) of the Internal Revenue Code of 1986 (Code). Those proposed regulations are withdrawn.

Temporary regulations in the rules and regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to section 368(a)(1)(A). The temporary regulations set forth certain definitions and explanations with respect to certain transactions that qualify as statutory mergers and consolidations. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

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

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 21, 2003, beginning at 10 a.m. in room 4718 of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight copies) by April 24, 2003. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Richard M. Heinecke, Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Withdrawal of Proposed Amendments

Accordingly, under the authority of 26 U.S.C. 7805, the proposed amendment to 26 CFR part 1 that was published in the **Federal Register** on Thursday, November 15, 2001 (66 FR 57400), is withdrawn.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. In § 1.368–2, paragraph (b)(1) is revised to read as follows:

§ 1.368–2 Definition of terms.

(The text of proposed § 1.368–2 is the same as the text of § 1.368–2T published elsewhere in this issue of the **Federal Register**.)

Approved: January 17, 2003.

David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

[FR Doc. 03–1545 Filed 1–23–03; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI112–01–7342a; FRL–7411–6]

Approval and Promulgation of Implementation Plans; Wisconsin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a revision to the Wisconsin regulations as they pertain to Northern Engraving Corporation (NEC) facilities in Holmen and Sparta, Wisconsin, as requested by the State of Wisconsin on June 12, 2002. This State Implementation Plan (SIP) revision makes changes to Wisconsin air pollution control rules federally enforceable. The rule revisions modify the emission limits adopted by the State which are part of the current Wisconsin SIP. The revised rules, specifically portions of the Environmental Cooperative Agreement with NEC, supercede portions of the rules in the Wisconsin SIP.

In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's request as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. The rationale for approval is set forth in the direct final rule. If EPA receives no written adverse comments, EPA will take no further action on this proposed rule. If EPA receives written adverse comment, we 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. In that event, EPA will address all relevant public comments in a subsequent final rule based on this proposed rule. In either event, EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Comments on this action must be received by February 24, 2003.

ADDRESSES: Written comments should be mailed to: Robert B. Miller, Chief, Permits and Grants Section, Air Programs Branch (AR–18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. A copy of the State's request is available for inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Constantine Blathras at (312) 886–0671.

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking today?
II. Where can I find more information about this proposal and corresponding direct final rule?

I. What Action Is EPA Taking Today?

The EPA is proposing to approve a revision to the Wisconsin regulations as they pertain to NEC's Holmen and Sparta, Wisconsin facilities as requested by the State of Wisconsin on June 12, 2002. The SIP revision makes changes to Wisconsin air pollution control rules federally enforceable. These rule changes were made at the request of NEC and the State of Wisconsin and they apply to the operation of the NEC Holmen and Sparta facilities. The rule revisions modify the emission limits adopted by the State of Wisconsin which are part of the current Wisconsin SIP. The rule revisions, portions of the Environmental Cooperative Agreement, supercede portions of rules in the Wisconsin SIP requiring a source-specific SIP revision.

II. Where Can I Find More Information About This Proposal and Corresponding Direct Final Rule?

For additional information see the direct final rule published in the rules and regulations section of this **Federal Register**.

Authority: 42 U.S.C. 4201 *et seq.*

Dated: October 24, 2002.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 03–1517 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 312

[FRL–7442–5]

RIN 2050–AF05

Clarification to Interim Standards and Practices for All Appropriate Inquiry Under CERCLA and Notice of Future Rulemaking Action

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a clarification to a provision included in recent amendments to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Specifically, today's proposed rule addresses the interim standard set by Congress in the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Law'') for conducting ''all appropriate inquiry'' to establish that a landowner had no reason to know of contamination at a property under CERCLA liability provisions prior to purchasing the property. EPA is proposing a clarification to the interim standard established in the Brownfields Law. The clarification is that in the case of property purchased on or after May 31, 1997, the requirements for conducting ''all appropriate inquiry,'' including the conduct of such activities to establish an innocent landowner defense under CERCLA, also will be satisfied through the use of ASTM Standard E1527–2000, entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.'' EPA is proposing that recipients of brownfields site assessment grants also will be in compliance with the all appropriate inquiry standards if they comply with the ASTM Standard E1527–2000.

DATES: EPA will accept public comments on this proposed rule until February 24, 2003. If we receive no adverse comment by this date, we will not take further action on this proposed rule. If we receive adverse comment, we will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action.

ADDRESSES: Comments on today's proposed rule may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions provided in paragraph I.B. of the **SUPPLEMENTARY INFORMATION** section below. Please reference Docket number SFUND–2002–0007 when submitting your comments.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA/CERCLA Call Center at 800–424–9346 or TDD 800–553–7672 (hearing impaired). In the Washington, DC metropolitan area, call 703–412–9810 or TDD 703–412–3323.

For more detailed information on specific aspects of this proposed rule, contact Patricia Overmeyer, Office of Brownfields Clean up and Redevelopment (5105T), U.S.

Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460–0002, 202–566–2774. *overmeyer.patricia@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

A. How Can I Get Copies Of The Background Materials Supporting Today's Proposed Rule or Other Related Information?

1. EPA has established an official public docket for this proposed rule under Docket ID No. SFUND–2002–0007. The official public docket consists of the documents specifically referenced in this proposed rule and other information related to this proposed rule. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center located at 1301 Constitution Ave. NW., EPA West Building, Room B–102, Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (202) 566–0276. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

You may use EPA Dockets at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI, and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified above.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff. For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA will not consider late comments in formulating a final decision.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the party submitting the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. SFUND–2002–0007. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

2. *E-mail.* Comments may be sent by electronic mail (e-mail) to *Superfund.Docket@epamail.epa.gov*. Make sure this electronic copy is in an ASCII format that does not use special characters or encryption. Cite the docket Number F–2002–0007 in your electronic file. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

3. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified above. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

4. *By Mail.* Send two (2) copies of your comments to: EPA Docket Center, U.S. Environmental Protection Agency Headquarters (EPA, HQ), Mail Code

5305T, 1200 Pennsylvania Ave., NW, Washington, DC, 20460, Attention Docket ID No. SFUND–2002–0007.

5. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center, EPA West Building Room No. B–102, 1301 Constitution Ave., NW., Washington, DC, 20004. Attention Docket ID No. SFUND–2002–0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified above.

Regulated Entities

Entities potentially regulated by this action include public and private parties who, as bona fide prospective purchasers, contiguous property owners, or innocent landowners, purchase property and intend to claim a limitation on CERCLA liability in conjunction with the property purchase. In addition, any entity conducting a site characterization or assessment with a brownfields grant awarded under CERCLA section 104(k)(2)(B)(ii) will be affected by today's action. This includes state, local and Tribal governments that receive brownfields site assessment grants. A summary of the potentially affected industry sectors (by NAICS codes) is displayed in the table below.

Industry category	NAICS code
Real Estate	531
Insurance	52412
Banking/Real Estate Credit	52292
Environmental Consulting Services	54162
State, Local and Tribal Government	N/A

The list of potentially affected entities in the above table may not be exhaustive. Our aim is to provide a guide for readers regarding those entities that EPA is aware potentially could be affected by this action. However, this action may affect other entities not listed in the table. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

Preamble

I. Statutory Authority
II. Background
III. Today's Action
IV. Future Rulemaking Setting Standards for ''All Appropriate Inquiry''
V. Statutory and Executive Order Reviews

I. Statutory Authority

This proposed rule clarifies provisions included in section 223 of the Small Business Liability Relief and Brownfields Revitalization Act which amends section 101(35)(B) of CERCLA (42 U.S.C. 9601(35)) and proposes to clarify interim standards for the conduct of ''all appropriate inquiry'' for obtaining CERCLA liability relief and for conducting site characterizations and assessments with the use of brownfields grant monies.

II. Background

On January 11, 2002, President Bush signed the Small Business Liability Relief and Brownfields Revitalization Act (''the Brownfields Act''). In general, the Act amends CERCLA and provides funds to assess and clean up brownfields sites; clarifies CERCLA liability provisions related to innocent purchasers of contaminated properties; and provides funding to enhance State and Tribal clean up programs. In part, subtitle B of Title II of the Act revises some of the provisions of CERCLA section 101(35) and provides some Superfund liability limitations for bona fide prospective purchasers and contiguous property owners, in addition to clarifying the requirements necessary to establish the innocent landowner defense under CERCLA. Among the requirements added to CERCLA is the requirement that such parties undertake ''all appropriate inquiry'into prior ownership and use of certain property.

The Brownfields Law requires EPA to develop regulations within two years which will establish standards and practices for how to conduct all appropriate inquiry. In addition, the Brownfields Law establishes interim standards for conducting all appropriate inquiry that will remain in effect until EPA promulgates regulations. Congress established, as the federal interim standard for conducting all appropriate inquiry, the procedures of the American Society for Testing and Materials (ASTM) including Standard E1527–97 (entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process''). This interim standard applies to properties purchased on or after May 31, 1997 until EPA promulgates federal regulations establishing standards and practices for conducting all appropriate inquiry.

EPA is proposing to clarify that persons may use the current ASTM standard, E1527–2000 for conducting all appropriate inquiry and establishing the innocent landowner defense under CERCLA section 101(35)(B) for properties purchased on or after May 31, 1997, while continuing also to recognize use of ASTM's previous standard, E1527–97.

Following enactment of the Brownfields Law, EPA received inquiries from interested parties expressing concerns that the ASTM standard for all appropriate inquiry that was cited in the law (*i.e.*, ASTM's 1997 standard) has been updated and consequently is no longer available from ASTM. The ASTM standard cited in the Brownfields Law has been updated and replaced with ASTM's revised standard, ''Standard E1527–2000.'' The revised standard has the same name as the previous standard. The revised standard is not significantly different from the previous standard. Revisions to the 1997 standard that are incorporated into the E1527–2000 updated standard include provisions for potential expansion of an assessment, guidance for better identification of the purpose of the assessment, a provision for inquiring about historical remediation, a provision for facilitating reconstruction of the assessment by a different assessor, and amended guidance for selecting an environmental professional. A summary of the revisions made to the 1997 ASTM standard and included in the 1527–2000 standard is provided in the document ''Overview of Additions and Modifications to ASTM 1527–2000 Standard from the 1997 ASTM Standard.'' A copy of this document, as well as an annotated copy of the 1997 ASTM standard identifying the specific modifications incorporated into the ASTM 2000 standard, is included in the regulatory docket for today's proposed rule.

EPA believes that it is consistent with Congressional intent to require the use of the most current standards available until EPA has promulgated its standard and not to require the use of standards that have been superseded or that generally are not available. In addition, Congress did not intend to place an undue burden on interested parties seeking to obtain and implement the standard. Given that the version of the ASTM standard cited in the Brownfields Law is no longer available, such an undue burden may occur, if EPA does not undertake today's action. In particular, recipients of grant monies awarded under the new Brownfields Law may experience an undue burden, if required to comply with the ASTM standard that no longer is available or recognized as the current industry standard. Therefore, with today's action, EPA is proposing that for the purposes of CERCLA section 101(35)(B), until the Agency promulgates regulations implementing standards for all appropriate inquiry parties may use either the procedures provided in ASTM E1527–2000, entitled ''Standard Practice for Environmental Site

Assessment: Phase I Environmental Site Assessment Process,'' or the standard ASTM E1527–97.

III. Today's Action

EPA is proposing to revise the interim standard for all appropriate inquiry to allow for the use of the ASTM 1527–2000 standard to reduce any undue burden placed upon brownfields grant recipients. The Agency views this as a noncontroversial action and anticipates no adverse public comment on this proposed revision. We believe that today's action is appropriate because it: (1) Allows for the use of the updated version of the standard cited in the Act, while not disallowing the use of the former version, and the updated version of the standard is similar to, and not significantly different than, the previous standard; (2) reduces the burden of obtaining an appropriate standard, given that the standard cited in the Brownfields Law is no longer available; and (3) this action merely clarifies an interim standard that is effective only until EPA promulgates a final rule replacing the interim standard.

Because we view today's action as noncontroversial, in the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing the clarification to the interim standard for all appropriate inquiry as a direct final rule. We are publishing the direct final rule without prior proposal because we view this as a noncontroversial clarification and we anticipate no adverse comment. We explain our reasons for this action above. If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We may address public comments in a subsequent final rule based on this proposal. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

IV. Future Rulemaking Setting Standards for ''All Appropriate Inquiry''

EPA also is announcing today its progress in developing regulatory standards for conducting ''all appropriate inquiry.'' The Brownfields Law requires that EPA promulgate such standards within two years of enactment of the law, or by January 2004. Congress included in the Brownfields Law a list of criteria that the Agency must address in the regulations establishing standards and practices for conducting all appropriate inquiry (section 101(35)(2)(B)(ii)). The Act also requires that parties receiving funding under the federal brownfields program to conduct site assessments must conduct the site assessment in accordance with the standards and practices for all appropriate inquiry established under the same provision of the Act.

EPA is soliciting the advice and input of public and private stakeholder groups in developing the regulations for conducting all appropriate inquiry in accordance with the criteria set forth by Congress. We understand that voluntary standards developed by standards developing organizations, such as the ASTM 1527–2000 standard, are available and are currently being used to conduct all appropriate inquiry in conjunction with private real estate property transactions. In addition, site assessment protocols have been established under the federal Superfund remedial action and RCRA corrective action programs, as well as within State clean up programs. We intend to develop federal regulations that build upon the depth of experience accrued in both the public and private sectors in implementing these standards and programs. We believe that building upon currently available private sector standards for undertaking all appropriate inquiry as well as building on the experience of state and federal government site assessment programs is the most efficient and economical way to develop federal regulatory standards that will both meet the criteria set in the Brownfields Law and ensure minimal disruption to the private market and state and federal site assessment programs.

To ensure that we obtain a diverse array of input from both private sector stakeholders and state program officials, EPA is developing the federal regulations by soliciting private and public sector input under the convening stage of the negotiated rulemaking process, and may supplement our information gathering through the conduct of public meetings. We initiated the convening stage of a negotiated rulemaking process to identify appropriate stakeholder groups and solicit advice and input from experienced public and private sector users of similar standards. Following an evaluation of stakeholder interest and input during the convening process, we either will announce our intent to continue with a negotiated rulemaking process, or announce our intent to solicit public input, by way of an additional notice or a public meeting, on options for a proposed rulemaking that will set standards for all appropriate inquiry. We anticipate announcing our intended approach for the development of a proposed rulemaking in the **Federal Register** by the winter of 2003. Any questions regarding our future regulatory effort should be directed to the parties listed above in the section entitled **FOR FURTHER INFORMATION CONTACT**.

V. Statutory and Executive Order Reviews

a. 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.

b. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 FR U.S.C. 3501 *et seq.*)

c. The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the APA 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. This action will not have a significant impact on a substantial number of small entities because it does not create any new requirements.

d. Because the purpose of today's action is to make a clarification that does not create any new requirements it has no economic impact and is not subject to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pubic Law 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.

e. 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).

f. This rule does not have tribal implications, as specified by Executive Order 13175 (65 FR 67249, November 6, 2000).

g. This rule is not subject to Executive Order 13045 (62 FR 1985, April 23, 1997), because it is not economically significant.

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

i. This action does involve technical standards; therefore, the requirements of

section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) apply. The NTTAA was signed into law on March 7, 1996 and, among other things, directs the National Institute of Standards and Technology (NIST) to bring together federal agencies as well as state and local governments to achieve greater reliance on voluntary standards and decreased dependence on in-house standards. It states that use of such standards, whenever practicable and appropriate, is intended to achieve the following goals: (a) Eliminate the cost to the government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation; (b) provide incentives and opportunities to establish standards that serve national needs; (c) encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards; and (d) further the policy of reliance upon the private sector to supply Government needs for goods and services. The Act requires that federal agencies adopt private sector standards, particularly those developed by standards developing organizations (SDOs), wherever possible in lieu of creating proprietary, non-consensus standards. Today's action is compliant with the spirit and requirements of the NTTAA, given that the interim standard for all appropriate inquiry that is the subject of today's action is a private sector standard developed by a standard developing organization. Today's action allows for the use of the American Society for Testing and Materials (ASTM) standard known as Standard E1527–2000 and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process'' as the interim standard for conducting all appropriate inquiry for properties purchased on or after May 31, 1997, or in the alternative, the use of Standard E1527–97, and entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process.''

j. Today's action does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

k. 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 submitted 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 March 25, 2003 unless EPA publishes a withdrawal in the **Federal Register**.

List of Subjects in 40 CFR Part 312

Environmental protection, Administrative practice and procedure, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 17, 2003.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, we propose to amend title 40 chapter J of the code of Federal Regulations as follows:

1. Title 40 Chapter J is amended by adding new part 312 to read as follows:

PART 312—INNOCENT LANDOWNERS, STANDARDS FOR CONDUCTING ALL APPROPRIATE INQUIRY

Subpart A—Introduction

Sec.
312.1 Purpose and applicability.
312.2 Standards and practices for all appropriate inquiry.

Subpart B—[Reserved]

Authority: Section 101(35)(B) of CERCLA, as amended, 42 U.S.C. 9601(35)(B).

Subpart A—Introduction

§ 312.1 Purpose and applicability.

(a) Purpose. The purpose of this section is to provide standards and procedures for ''all appropriate inquiry'' for the purposes of CERCLA section 101(35)(B).

(b) *Applicability.* This section is applicable to: potential innocent landowners conducting all appropriate inquiry under section 101(35)(B) of CERCLA; bona fide prospective purchasers definedunder section 101(40) of CERCLA; contiguous property owners under section 107(q) of CERCLA; and persons conducting site characterization and assessments with the use of a grant awarded under CERCLA section 104(k)(2)(B)(ii).

§ 312.2 Standards and practices for all appropriate inquiry.

(a) With respect to property purchased on or after May 31, 1997, the procedures of the American Society for Testing and Materials (ASTM) 1527–97 and the procedures of the American Society for Testing and Materials (ASTM) 1527–2000, both entitled ''Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process,'' shall satisfy the requirements for conducting ''all appropriate inquiry'' under section 101(35)(B)(i)(I) of CERCLA, as amended by the Small Business Liability Relief and Brownfields Revitalization Act.

[FR Doc. 03–1630 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–6012–N4]

RIN 0938–AM40

Medicare Program; Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics; Meeting Announcement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meetings.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces additional public meetings of the Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics. The Committee was mandated by section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).

DATES: The next two negotiated rulemaking committee meetings will be held March 10 and 11, from 9 a.m. to 5 p.m. e.s.t. and April 7 and 8, 2003 from 8 a.m. to 4 p.m. e.s.t.

These meetings are open to the public, and subsequent meetings will be announced in the **Federal Register**.

ADDRESSES: The Committee meetings will be held at the Hilton Pikesville at 1726 Reisterstown Road, Baltimore, MD 21208 (Telephone 410–653–1100). Any subsequent meetings will be held at locations to be announced.

FOR FURTHER INFORMATION CONTACT: Theresa Linkowich, (410) 786–9249 (General inquiries concerning prosthetics and custom-fabricated orthotics), Centers for Medicare & Medicaid Services (CMS), 7500 Security Blvd, Baltimore MD 21244; or Lynn Sylvester, 202–606–9140, Federal Mediation and Conciliation Services, 2100 K Street, NW., Washington, DC 20427; or Ira Lobel, 518–431–0130, Federal Mediation and Conciliation Services, Clinton Square, Room 952, Albany, NY 12207

SUPPLEMENTARY INFORMATION: We published a document in the **Federal Register** on July 26, 2002 (FR pages 48839–48840) announcing the establishment of the negotiated rulemaking committee to advise us on developing a proposed rule that would establish special payment provisions and requirements for suppliers of prosthetics and certain custom-fabricated orthotics under the Medicare program. The notice also announced dates for the Committee's first two meetings on October 1–3, 2002 and October 29–31, 2002. On November 22, 2002 (FR page 70358), a notice of meetings was published in the **Federal Register** announcing the third meeting held January 6 and 7, 2003, and the fourth meeting which will be held February 10 and 11, 2003.

Through face-to-face negotiations, these meetings will help the Committee to reach consensus on the substance of the proposed rule. If consensus is reached, the Committee will transmit to us a report containing required information for developing a proposed rule and we will use the report as the basis for the proposed rule. The Committee is responsible for identifying the key issues, gauging their importance, analyzing the information necessary to resolve the issues, arriving at a consensus, and recommending the text and content of the proposed regulation. Detailed information is available on the CMS Internet Home Page: *http://cms.hhs.gov/faca/prosthetics/* or by calling the Federal Advisory Committee Hotline at (410) 786–9379.

The Agendas for the March 10 and 11 meeting and April 7 and 8 meeting will cover the following:

1. Review of the February 10 and 11 minutes. (March 10 and 11) and review of the March 10 and 11 minutes (April 7 and 8).
2. Discussion of statutory terms to be further defined by regulation.
3. Discussion on L codes.
4. Discussion on supplier and practitioner qualifications as set forth in the statute.
5. Presentation of Computer Assisted Design (CAD)
6. Presentation by National Orthotic Manufacturers Association (NOMA)
7. Oral comments from members of the public.

Public Participation

All interested parties are invited to attend these public meetings, but attendance is limited to the space available. No advance registration is required. Seating will be available on a first-come first-served basis. Individuals requiring sign language interpretation for the hearing impaired or other special accommodations should contact Theresa Linkowich, *tlinkowich@cms.hhs.gov* or call (410) 786–9249 at least 10 days before the meeting. The Committee has the authority to decide to what extent oral presentations by members of the public may be permitted at the meeting. Oral presentations will be limited to statements of fact and views, and shall not include any questioning of the Committee members or other participants unless the facilitators have specifically approved these questions. The number of oral presentations may be limited by the time available.

Interested parties can file statements with the Committee. Mail written statements to the following address: Federal Mediation and Conciliation Services, 2100 K Street, NW., Washington, DC 20427, Attention: Lynn Sylvester, or call Lynn Sylvester at (202) 606–9140.

Additional Meetings

Meetings will be held as necessary. We will publish notices of future meetings in the **Federal Register**. All future meetings will be open to the public without advance registration.

Authority: Federal Advisory Committee Act (5 U.S.C. App. 2) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 17, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1651 Filed 1–23–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 030114011–3011–01, I.D. 122702A]

Petition To Designate Alaska Transient Killer Whales as Depleted; Finding

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

ACTION: Notice of finding; request for information.

SUMMARY: NMFS received a petition to designate a group of transient killer whales as depleted under the Marine Mammal Protection Act (MMPA). This group of killer whales, identified as the AT1 group, inhabits Prince William Sound/Kenai Fjords, AK. NMFS finds that the petition presents substantial information indicating that the petitioned action may be warranted and will initiate a status review promptly. NMFS solicits information and comments from the public that may contribute to the status review.

DATES: Information and comments on the action must be received by March 10, 2003.

ADDRESSES: A copy of the petition may be requested from, and information and comments on this action should be submitted to, Assistant Administrator for Protected Resources, NMFS, 709 W. 9th St, Juneau, AK 99802–1668. Comments will not be accepted if submitted via email or the Internet; however, comments may be sent via fax to (907) 586–7012.

FOR FURTHER INFORMATION CONTACT: Kaja Brix, NMFS, Alaska Region (907) 586–7235 or Tom Eagle, NMFS, Office of Protected Resources, (301) 713–2322 ext. 105.

SUPPLEMENTARY INFORMATION:

Electronic Access

Reference materials regarding this rule, including the petition, its attachments, and marine mammal stock assessment reports, may be obtained from the Internet at http://www.fakr.noaa.gov.

Background

A stock is depleted under the MMPA when its abundance is below optimum sustainable population (OSP) levels. OSP is the population size that falls within a range from the population level of a given species or stock which is the

largest supportable within the ecosystem (carrying capacity or K) to the population level that results in the maximum net productivity level (MNPL). MNPL is the greatest net annual increment in population numbers resulting from additions to the population due to reproduction less losses due to natural mortality. Historically, MNPL has been expressed as a range of values (between 50 and 70 percent of the carrying capacity (K)) determined theoretically by estimating what stock size, in relation to the original stock size, will produce the maximum net increase in population (42 FR 12010, March 1, 1977). NMFS has used the mid-point of this range (i.e. 60 percent of K) to determine whether a stock is depleted (42 FR 64548, December 27, 1977; 45 FR 72178, October 31, 1980).

On November 13, 2002, NMFS received a petition from the Alaska Center for the Environment, Alaska Community Action on Toxics, Center for Biological Diversity, Coastal Coalition, Defenders of Wildlife, the Eyak Preservation Council, and the National Wildlife Federation, to designate the AT1 group of transient killer whales (Orcinus orca) as a depleted stock under the MMPA. The petitioners note that the AT1 group of killer whales is currently considered part of the eastern North Pacific transient killer whale stock. However, they present information to support their assertion that the AT1 group is a separate stock. The petitioners also present information to support their assertion that this group of killer whales is depleted. Copies of the petition are available from NMFS (see **ADDRESSES** and Electronic Access).

Pursuant to Section 115(a)(3)(A) of the MMPA, NMFS published a notice in the **Federal Register** that the petition had been received and was available for public review (67 FR 70407, November 22, 2002). In response to its announcement that the petition had been received, NMFS received numerous comments from the public. These comments urge NMFS to designate AT1 killer whales as a depleted stock. None of the comments, however, contained substantive information in addition to the information contained in the petition. Therefore, responses to the comments are not necessary.

Section 115(a)(3)(B) of the MMPA requires NMFS to publish a notice in the **Federal Register** as to whether the petition presents substantial information indicating that the petitioned action may be warranted. After reviewing information presented in the petition, which is summarized in the next section of this notice, NMFS finds that the petitioners present substantial information indicating that the petitioned action may be warranted.

As required by the MMPA, NMFS will promptly begin a status review of AT1 killer whales. NMFS must publish a proposed rule as to the status of the stock no later than 210 days after receipt of the petition. The status review will address whether the AT1 group is a separate stock under the MMPA and whether this potential stock is depleted.

The Petition

The petition presents information on the classification of killer whales in general and of the AT1 killer whales in particular. The petition also presents information on the changes in the size of the group over the last 20 years and identifies potential causes of decline in numbers of these animals.

Killer whales of the North Pacific are generally classified by type: resident, transient, or offshore. Little information is available on the offshore animals due to the difficulty of studying these whales. Resident killer whales are well studied, as are some groups of transients.

The main distinguishing feature between the residents and transients is their mutually exclusive prey base, with residents eating fish and transients consuming marine mammals. These two types of killer whales may be found in overlapping geographic ranges; however, they do not interact. The primary social structure of both groups is the matriline, dominated by a matriarchal female, her offspring, and direct descendants.

Permanently associating matrilines are generally termed pods. Animals remain within the pod for life, and breeding apparently takes place between whales from different pods. Pods of whales can be distinguished genetically, by within-group associations and based on acoustic patterns. Although transient whales tend to form looser associations than residents (and as such the ''pod'' terminology is not applied to transients), they can nevertheless be distinguished based on similar genetic and demographic factors.

AT1 killer whales are transients. In NMFS' marine mammal stock assessment reports, AT1 killer whales are currently included with two other groups of transient killer whales in the eastern North Pacific stock (Angliss et al. 2001). The eastern North Pacific stock of transient killer whales is comprised of the west coast transients found from northern Southeast Alaska to central California; the Gulf of Alaska transients; and the AT1 transients.

Although the range of these transient groups overlap, they do not associate. The Gulf of Alaska and AT1 whales inhabit the waters of Alaska exclusively. The Gulf of Alaska transients are occasionally found in Prince William Sound, whereas the AT1 group inhabits the waters of Prince William Sound and the Kenai Fjords and has not been observed elsewhere.

AT1 Killer Whales as a Separate Stock

The petitioners suggested that the AT1 group of killer whales was a separate stock based upon genetic and behavioral information and argued that the AT1 group should be managed separately. Petitioners provided detailed discussion of information supporting the identification of AT1 killer whales as a separate stock in a letter to NMFS dated July 18, 2002, which was a comment on NMFS' draft 2002 marine mammal stock assessment reports. That letter was incorporated by reference into the petition.

The petitioners suggested that evidence from analyses of mitochondrial DNA indicated that females do not emigrate from or immigrate to the AT1 group. The petitioners also suggested that nuclear DNA from analyses of microsatellites indicated a lack of male or female mediated gene flow between the AT1 group and other groups of killer whales.

The petitioners stated that AT1 transients have never been seen with other transient killer whales. The AT1 group has been sighted only in the waters of Prince William Sound and the Kenai Fjords, and other transient killer whales occupy these areas only occasionally. The petitioners also noted that AT1 transients are most frequently seen foraging near shore, and other transient killer whales are less frequently seen near shore.

Further, petitioners noted that the AT1 group is readily distinguishable from other transient killer whales in the Gulf of Alaska in hunting and communication patterns. Whereas other transient killer whales prey extensively upon Steller sea lions, AT1 transients prey primarily on harbor seals and Dall's porpoise. The petitioners concluded that these genetic and behavioral differences are sufficient evidence upon which to identify the AT1 group as a separate population stock. The petitioners also noted that the Alaska Scientific Review Group, an independent advisory group established according to section 117 of the MMPA, has recommended that NMFS recognize the AT1 group as a separate stock.

AT1 Group as Depleted

Information on AT1 population size included in the petition shows that this group of whales numbered 22 animals in 1984, with the last calf being born in that year. The group now numbers 9 animals; less than half the size of the population prior to the Exxon Valdez oil spill in 1989. Two adult males in the group have been confirmed dead in the last 2 years. The current composition includes only 4 females, 2 of which are reproductively senescent.

Using the definition of depleted described above (see Background) and assuming a conservative estimate of K at the historical abundance level of 22 animals, the petitioners suggested that the current abundance of 9 animals is below OSP (i.e, less than 60 percent of the historical abundance, which is 13 animals) and, therefore, that the AT1 group of killer whales is depleted.

The petitioners present several factors that they consider may be causes of the decline of the AT1 group: the Exxon Valdez oil spill; chemical contaminants; increased vessel traffic; and reduction in available prey species. Crude oil exposure could be a factor in the decline of AT1 whales as they were seen immediately after the 1989 Exxon Valdez spill swimming in the crude oil around the tanker. Chemical contamination may also play a role in their decline. Analysis of blubber samples from the male AT1 group member that died in 2000 showed very high levels of contaminants. The AT1 group may also be exposed to increasing underwater vessel noise as the number of vessels with access to Prince William Sound increases due to the recent road access to Whittier. Finally, the harbor seal population in Prince William Sound, one of the main prey items of the AT1 group, has declined substantially in the past, and recently harbor seal numbers have continued declining at about eight percent per year.

Status Review

As the initial task under the upcoming status review, NMFS must evaluate the information in the petition and other information related to whether or not AT1 killer whales are a separate population stock. If NMFS determines that the AT1 group is a separate stock, NMFS would then evaluate whether it is depleted under the MMPA. NMFS is aware of the information related to abundances in 1984 and the present and is not aware of additional information related to historical or current abundance. NMFS notes that the Marine Mammal Commission has advised that the AT1 group should be recognized as a separate population stock and that it is below its MNPL.

Information Solicited

NMFS solicits comments and information related to this petition and the status of AT1 killer whales. NMFS is specifically interested in comments and additional information related to (1) the identification of AT1 killer whales as a population stock, (2) the historical or current abundance of this group, (3) factors that may be affecting the group, and (4) conservation measures that may promote their recovery.

Authority: Authority: 16 U.S.C. 1361 *et seq.*

Dated: January 17, 2003.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 03–1650 Filed 1–23–03; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 021213310–2310–01; I.D. 101702B]

RIN 0648–AP92

Individual Fishing Quota (IFQ) Program for Pacific Halibut and Sablefish; Revisions to Recordkeeping and Reporting Requirements

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement Amendment 72 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (Amendment 72) and Amendment 64 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (Amendment 64) (collectively, Amendments 72/64). This action would revise certain recordkeeping and reporting requirements for the Individual Fishing Quota (IFQ) Program for fixed gear Pacific halibut and sablefish fisheries and the Western Alaska Community Development Quota (CDQ) Program for the Pacific halibut fishery. This action is necessary to improve IFQ fishing operations, while complying with IFQ Program requirements; to improve NMFS' ability to efficiently administer the program; and to improve the clarity and consistency of IFQ Program regulations. This action is intended to meet the conservation and management requirements of the Northern Pacific Halibut Act of 1982 (Halibut Act) with respect to halibut and of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.,* (Magnuson-Stevens Act) with respect to sablefish and to further the goals and objectives of the groundfish Fishery Management Plans (FMPs).

DATES: Comments must be received at the following address no later than February 24, 2003.

ADDRESSES: Comments should be sent to Sue Salveson, Assistant Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668, Attn: Lori Gravel-Durall) or delivered to the Federal Building, 709 West 9th Street, Room 401, Juneau, AK. Comments may be sent via facsimile to 907–586–7465. Comments will not be accepted if submitted via e-mail or the Internet. Copies of Amendment 72/64 of the FMPs and the Regulatory Impact Review/Initial Regulatory Flexibility Analysis (RIR/IRFA) prepared for this action may also be obtained from the same address, or by calling the Alaska Region, NMFS, at 907–586–7228. Send comments on collection-of-information requirements to NMFS, Alaska Region, and to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB), Washington, DC 20503 (Attn: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Patsy A. Bearden, 907–586–7228 or *patsy.bearden@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background and Need for Action

NMFS manages the groundfish fisheries in the Exclusive Economic Zone (EEZ) off Alaska according to fishery management plans prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson-Stevens Act. The FMPs are implemented by regulations at 50 CFR part 679. General regulations that also pertain to these fisheries appear in subpart H to 50 CFR part 600.

Regulations codified at 50 CFR part 679 implement the IFQ Program, a limited access system for management of the Pacific halibut (*Hippoglossus stenolepis*) and sablefish (*Anoplopoma fimbria*) fixed gear fisheries in and off Alaska.

The IFQ Program, a limited access management system for the fixed gear Pacific halibut and sablefish fisheries off Alaska, was approved by NMFS in January 1993 and fully implemented beginning in March 1995. The IFQ Program for the sablefish fishery is implemented by the FMPs and Federal regulations under 50 CFR part 679 under authority of the Magnuson-Stevens Act. The IFQ Program for the halibut fishery is implemented by Federal regulations promulgated under the authority of the Halibut Act. Further information on the rationale for and implementation of the IFQ Program is contained in the preamble to the final rule published in the **Federal Register**, November 9, 1993 (58 FR 59375). Regulations implementing the IFQ Program have been revised numerous times since 1993 to refine program operations.

This action would amend the regulatory text establishing Recordkeeping and Reporting (R&R) requirements for the groundfish fishery as well as the IFQ program requirements. Removal of the IFQ Shipment Report and of the IFQ Vessel Clearance would affect other IFQ procedures and forms—the IFQ Landing Report, IFQ Prior Notice of Landing (PNOL), and IFQ Departure Report—as well as definitions, groundfish R&R procedures and forms, the Product Transfer Report (PTR) and Vessel Activity Report (VAR). Revisions are made to the regulatory text to accommodate the procedural changes.

The need, justification, and economic impacts for the actions in this proposed rule, as well as impacts of the alternatives considered, were analyzed in the RIR/IRFA prepared for this action (*see* **ADDRESSES**).

The revisions to the regulations at 50 CFR part 679 are presented below in the order they appear in the regulations.

Section 679.2 Definitions

This action would revise the definitions: ''Authorized officer,'' ''Clearing officer,'' ''IFQ landing,'' and ''IFQ Registered Buyer.'' ''Authorized officer,'' would be revised to cross-reference the definition of ''Authorized officer'' at 50 CFR 600.10.

Location	Existing text	Proposed text
Definition for ''Authorized officer''.	Authorized officer means, for purposes of recordkeeping and reporting, a NOAA special agent, a NOAA fishery enforcement officer or USCG fisheries enforcement personnel.	Means: (1) Any commissioned, warrant, or petty officer of the USCG; (2) Any special agent or fishery enforcement officer of NMFS; (3) Any officer designated by the head of any Federal or State agency that has entered into an agreement with the Secretary and the Commandant of the USCG to enforce the provisions of the Magnuson-Stevens Act or any other statute administered by NOAA; or (4) Any USCG personnel accompanying and acting under the direction of any person described in paragraph (1) of this definition.
Definition for ''Clearing officer''	Means a NMFS special agent, a NMFS fishery enforcement officer, or a NMFS enforcement aide who performs the function of clearing vessels at one of the primary ports listed in Table 14 to this part.	Means a NOAA Fisheries Office for Law Enforcement (OLE) special agent, an OLE fishery enforcement officer, or an OLE enforcement enforcement aide.
Definition for ''IFQ landing''	Means the unloading or transferring of any IFQ halibut, IFQ sablefish, or produts thereof from the vessel that harvested such fish or the removal from the water of a vessel containing IFQ halbiut, IFQ sablefish, or products thereof.	Means the unloading or transferring of any IFQ halibut, CDQ halibut, IFQ sablefish, or products thereof from vessel that harvested such fish or the removal from the water of a vessel containing IFQ halibut, CDQ halibut, IFQ sablefish, or products thereof.
Definition for ''IFQ permit holder''.	§ 679.4(d)(3)(B)	§ 679.4(d)(1).
Definition for ''IFQ Registered Buyer''.	§ 679.4(d)(2)	§ 679.4(d)(3).
Definition for ''Transfer''	(2) *IFQ/CDQ fisheries.* Any loading, offloading, shipment or receipt of any groundfish product.	(2) *IFQ halibut, CDQ halibut, IFQ sablefish.* Any loading, offloading, shipment or receipt of any IFQ halibut, CDQ halibut, IFQ sablefish product.

Section 679.4(d) IFQ Permits

In response to the removal of ''Vessel Clearance'' and ''Shipment Report'' and to the revision of ''Departure Report,'' this action would reorganize the regulatory text in the IFQ permits section. Detailed changes to § 679.4(d) are presented below:

§ 679.4 paragraph	Redesignated as	No change	Revised	Removed	Added
(d) heading	.....	.....	X		
Introductory (d)(1)	Introductory (d).				
(d)(1) heading	.....	.....	X		
(d)(1)(i)	(d)(1)	.....	X	.....	
(d)(4)(i)	(d)(1)(i).				
(d)(6)(i)	(d)(1)(ii)	.....	X		
(d)(2) heading	.....	.....	X		
(d)(4)(ii)	(d)(2)(i)	.....	X		
(d)(1)(ii)	(d)(2)(ii)	.....	X		
(d)(3)(i)(C)	(d)(2)(iii)	.....	X		
(d)(3) heading	.....	.....	X		
(d)(2)	(d)(3).				

§ 679.4 paragraph	Redesignated as	No change	Revised	Removed	Added
(d)(4)(iii)	(d)(3)(i)		X		
(d)(3)(i)(B)				X	
Introductory (d)(2)	(d)(3)(ii).				
(d)(2)(i)	(d)(3)(ii)(A).				
(d)(2)(ii)	(d)(3)(ii)(B).				
(d)(2)(iii)	(d)(3)(ii)(C)		X		
(d)(3)(ii)	(d)(3)(iii)		X		
(d)(3)(iv)					X
(d)(4) heading			X		
(d)(3)(i)(A)	(d)(4).				
(d)(5)			X		
(d)(6)(i)				X	
(d)(6)(ii)	(d)(6)(i)		X		
(d)(6)(iii)	(d)(6)(ii)		X		
(d)(7)			X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.4 paragraph	Existing text	Proposed text
(d) heading	IFQ Permits.	IFQ permits, IFQ cards, and IFQ Registered Buyer permits.
(d)(1) heading	General.	IFQ permit.
(d)(1)(i)	(d)(4)(i) *IFQ permit.* An IFQ permit authorizes the person identified on the permit to harvest IFQ halibut or IFQ sablefish from a specified IFQ regulatory area at any time during an open fishing season during the fishing year for which the IFQ permit is issued until the amount harvested is equal to the amount specified under the permit, or until it is revoked, suspended, or modified under 15 CFR part 904.	(d)(1)(i) An IFQ permit authorizes the person identified on the permit to harvest IFQ halibut or IFQ sablefish from a specified IFQ regulatory area at any time during an open fishing season during the fishing year for which the IFQ permit is issued until the amount harvested is equal to the amount specified under the permit, or until it is revoked, suspended, or modified under 15 CFR part 904.
(d)(1)(ii)	(d)(1)(i) A copy of an IFQ permit that specifies the IFQ regulatory area and vessel category in which IFQ halibut or IFQ sablefish may be harvested by the IFQ permit holder; and (d)(6)(i) IFQ permit. A legible copy of any IFQ permit issued under this section must be carried on board the vessel used by the permitted person to harvest IFQ halibut or IFQ sablefish at all times that such fish are retained on board.	(d)(1)(ii) A legible copy of any IFQ permit that specifies the IFQ regulatory area and vessel length overall from which IFQ halibut or IFQ sablefish may be harvested by the IFQ permit holder must be carried on board the vessel used by the permitted person to harvest IFQ halibut or IFQ sablefish at all times that such fish are retained on board.
(d)(2) heading	Registered buyer permit.	IFQ card.
(d)(2)(i)	(d)(4)(ii) *IFQ card.* An IFQ card authorizes the individual identified on the card to land IFQ halibut or IFQ sablefish for debit against the specified IFQ permit until the card expires, or is revoked, suspended, or modified under 15 CFR part 904, or cancelled on request of the IFQ permit holder.	(d)(2)(i) An IFQ card authorizes the individual identified on the card to land IFQ halibut or IFQ sablefish for debit against the specified IFQ permit until the card expires, or is revoked, suspended, or modified under 15 CFR part 904, or cancelled on request of the IFQ permit holder.
(d)(2)(ii)	(d)(1)(ii) *IFQ card.* An original IFQ card issued by the Regional Administrator. (d)(6)(ii) *IFQ card.* Except as specified in 679.42(d), an individual that is issued an IFQ card must remain aboard the vessel used to harvests IFQ halibut or IFQ sablefish with that card during all fishing operations until arrival at the point of landing and during all IFQ landings.	(d)(2)(ii) An original IFQ card issued by the Regional Administrator must be on board the vessel that harvests IFQ halibut or IFQ sablefish at all times that such fish are retained on board. Except as specified in 679.42(d), an individual that is issued an IFQ card must remain aboard the vessel used to harvest IFQ halibut or IFQ sablefish with that card during the IFQ fishing trip and at the landing site during all IFQ landings.
(d)(2)(iii)	(d)(3)(i)(C) *IFQ card.* Each IFQ card issued by the Regional Administrator will display an IFQ permit number and the individual authorized by the IFQ permit holder to land IFQ halibut or IFQ sablefish for debit against the permit holder's IFQ.	(d)(2)(iii) Each IFQ card issued by the Regional Administrator will display an IFQ permit number, the name of the individual authorized by the IFQ permit holder to land IFQ halibut or IFQ sablefish for debit against the permit holder's IFQ. In addition, IFQ cards issued to hired masters representing permit holders per 679.42(i) and (j) will also display the ADF&G vessel identification number of the authorized vessel.
(d)(3) heading	How do I obtain an IFQ permit, IFQ card, or Registered Buyer Permit?	Registered Buyer permit.
(d)(3)(ii)(C)	(d)(2)(iii) A vessel operator who obtains a vessel clearance or submits a departure report (see 679.5(1)(5)(iv).	(d)(3)(ii)(C) A vessel operator who submits a Departure Report (see 679.5(l)(4)).
(d)(3)(iii)	(d)(3)(ii) *Registered Buyer permits.* Registered buyer permits will be renewed or issued annually by the Regional Administrator to persons that have a registered buyer application approved by the Regional Administrator.	(d)(3)(iii) A Registered Buyer permit is issued on a 3-year cycle by the Regional Administrator to persons that have a Registered Buyer application approved by the Regional Administrator.

Location § 679.4 paragraph	Existing text	Proposed text
(d)(4) heading	Duration.	Issuance.
(d)(5)	The IFQ permits issued under this section are not transferable, except as provided under 679.41. IFQ cards and Registered Buyer permits issued under this paragraph (d) are not transferable.	The quota shares and IFQ issued under this section are not transferable, except as provided under 679.41. IFQ cards and Registered Buyer permits issued under this paragraph (d) are not transferable.
(d)(6)(i)	(d)(6)(ii) *IFQ card.* Except as specified in § 679.42(d), an individual who is issued an IFQ card must remain aboard the vessel used to harvest IFQ halibut or IFQ sablefish with that card during all fishing operations until arrival at the point of landing and during all IFQ landings. The IFQ cardholder must present a copy of the IFQ permit and the original IFQ card for inspection on request of any authorized officer, clearing officer, or registered buyer purchasing IFQ species. Nothing in this paragraph would prevent an individual who is issued an IFQ card from being absent from the vessel used to harvest IFQ halibut or IFQ sablefish between the time the vessel arrives at the point of landing until the commencement of landing.	(d)(6)(i) *IFQ permit and card.* The IFQ cardholder must present a copy of the IFQ permit and the original IFQ card for inspection on request of any authorized officer or Registered Buyer receiving IFQ species. Nothing in this paragraph would prevent an individual who is issued an IFQ card from being absent from the vessel used to harvest IFQ halibut or IFQ sablefish from the time the vessel arrives at the point of landing and the commencement of landing.
(d)(6)(ii)	(d)(6)(iii) *Registered buyer permit.* A legible copy of the Registered Buyer permit must be present at the location of an IFQ landing and must be made available for inspection on request of any authorized officer or clearing officer.	(d)(6)(ii) *Registered Registered buyer permit.* A legible copy of the Registered Buyer permit must be present at the location of an IFQ landing and must be made available by the Registered Buyer's representative for inspection on request of any authorized officer.
(d)(7)	§ 679.5(e)(7)(ii).	§ 679.5(l)(7)(ii).

Section 679.5(a)(15) IFQ/groundfish Transfer Document Comparison

In response to the removal of the IFQ Vessel Clearance and the IFQ Shipment Report, the regulatory text in § 679.5(a)(15), the revised procedures for the Product Transfer Report, and the in-text table that compares the transfer documents are reorganized and revised.

The introductory paragraph (a)(15) of this section would be revised to include an explanation of the ''X'' symbols in the body of the table.

The in-text table would be restructured to provide for the removal of the IFQ Vessel Clearance and the IFQ Shipment Report. The columns across the top of the table are revised by removing the columns entitled: ''IFQ Vessel Clearance'' and ''IFQ Shipment Report,'' and adding columns entitled: ''IFQ Landing Report Receipt.'' Cross-referencing paragraph numbers previously located within table columns are relocated to rows in the table for easier reading. New headings are added to indicate activity, *e.g.*, submitting a report to NMFS, issuing a receipt to the public, and possessing a receipt. A new column heading ''SUBMITTAL'' would be added to group together those forms that require submittal to NMFS over the subheadings ''VAR,'' ''PTR,'' ''IFQ Trans-shipment Authorization,'' and ''IFQ Departure Report.'' Another new column heading ''ISSUE'' would be placed over the subheading ''IFQ Dockside Sales Receipt.'' A third heading ''POSSESS'' would be placed over the subheading ''IFQ Landing Report Receipt.'' The rows of the table are revised as follows:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
(a)(15) heading			X		
(a)(15)(i)			X		
(a)(15)(iii)	(a)(15)(ii)		X		
(a)(15)(iv)	(a)(15)(iii)		X		
(a)(15)(v)	(a)(15)(iv)		X		
(a)(15)(vi)	(a)(15)(v)		X		
(a)(15)(vii)	(a)(15)(vi)		X		
(a)(15)(vii)					X
(a)(15)(viii)			X		

Section 679.5(g) Product Transfer Report (PTR)

Currently, the groundfish PTR is used to document movement of groundfish product from a shoreside facility or from a processor vessel, while the IFQ Shipment Report is used to document IFQ fish transfer from an IFQ Registered Buyer. This action would combine the groundfish PTR and the IFQ Shipment Report into one form, a revised PTR, that would be used to document transfer of non-IFQ groundfish, donated prohibited species, all halibut and all sablefish. Although a copy of the Shipment Report currently is required to accompany the IFQ shipment, the proposed action would remove this requirement when using a PTR.

The detailed changes to the regulations describing the PTR are presented below:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
(g) heading			X		
(g)(2)(iii)	(g)(1)		X		

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
(g)(1)(i), (ii), (iii), and (iv)			X		
(g)(1)(v) heading					X
(g)(1)(v)(A)					X
(l)(3)(iv)	(g)(1)(v)(B)		X		
(l)(3)(i)(D)	(g)(1)(vi)		X		
Introductory (g)(2)			X		
(g)(2), (g)(2)(i), (ii), (iii)			X		
Introductory (g)(3)				X	
(g)(3)(i)		X			
(g)(3)(ii)			X		
(g)(3)(iii), (iv)				X	
(g)(4) heading			X		
(g)(4)(i)(A), (B)				X	
(g)(4)(ii)(A)	Introductory (g)(4)		X		
(g)(5), (g)(6)	(g)(6), (g)(7)				
Introductory (g)(5)	Introductory (g)(6)		X		
(g)(5)(i)	(g)(6)(i)		X		
(g)(5)(v)	(g)(6)(ii)		X		
(g)(5)(ii)	(g)(6)(iii)		X		
(g)(5)(iii)	(g)(6)(iv)		X		
(g)(5)(iv)	(g)(6)(v)		X		
(g)(6)(i)	(g)(7)(i)		X		
(g)(6)(ii)	(g)(7)(ii)		X		
New (g)(5) heading					X
(g)(4)(ii)(B)				X	
(g)(4)(ii)(C)	New introductory (g)(5)		X		
New (g)(5)(i), (ii), (iii), (iv)					X

The in-text table (new paragraph (g)(5)(iv)) of this section would be revised by separating the information into more distinct categories by dividing the columns to read ''Receiver,'' ''Date & time of product transfer,'' ''Location of product transfer,'' and ''Mode of transportation and intended route.'' Existing information would be reformatted to fit within these columns.

Section 679.5(k) Vessel Activity Report (VAR)

The VAR documents whether a vessel has onboard any fish or fish products, regardless of species. The VAR is submitted to NMFS before the vessel crosses the seaward boundary of the EEZ off Alaska or crosses the U.S.-Canada international boundary between Alaska and British Columbia. This action would revise the procedure for interaction of the VAR with IFQ reports due to the removal of the IFQ Vessel Clearance and the IFQ Shipment Report.

Detailed changes in § 679.5(k)(1) are presented below:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
Introductory (k)(1)	(k)(1)(i)		X		
(k)(1)(i)	(k)(1)(ii)		X		
(k)(1)(ii)	(k)(1)(iii)		X		
(k)(1)(iv)			X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.5, paragraph	Current text	Proposed text
(k)(1)(i)	Introductory (k)(1) Except as noted in paragraphs (k)(1)(iii) and (iv) of this section, the operator of a catcher vessel greater than 60 ft (18.3 m) LOA, a catcher/processor, or a mothership holding a Federal fisheries permit issued under this part and carrying fish or fish product onboard must complete and submit a VAR by FAX or electronic file to OLE, Juneau, AK before the vessel crosses the seaward boundary of the EEZ off Alaska or crosses the U.S.-Canadian international boundary between Alaska and British Columbia.	(k)(1)(i) *Fish or fish product onboard.* Except as noted in paragraph (k)(1)(iv) of this section, the operator of a catcher vessel greater than 60 ft (18.3 m) LOA, a catcher/processor, or a mothership required to hold a Federal fisheries permit issued under this part and carrying fish or fish product onboard must complete and submit a VAR by FAX or electronic file to OLE, Juneau, AK (907–586–7313) before the vessel crosses the seaward boundary of the EEZ off Alaska or crosses the U.S.-Canadian international boundary between Alaska and British Columbia.
(k)(1)(ii)	(k)(1)(i) *Both groundfish and IFQ fish.* If a vessel is carrying both groundfish and IFQ halibut or IFQ sablefish, the operator must submit a VAR in addition to a Vessel Departure Report (VDR) or a Vessel Clearance (VC).	(k)(1)(ii) *Combination of non-IFQ groundfish, IFQ halibut, CDQ halibut, and IFQ sablefish.* If a vessel is carrying non-IFQ groundfish and IFQ halibut, CDQ halibut or IFQ sablefish, the operator must submit a VAR in addition to an IFQ Departure Report per paragraph (1)(4) of this section.
(k)(1)(iii)	(k)(1)(ii) *Revised VAR.* If groundfish are landed at a port other than the one specified, submit a revised VAR showing the actual port of landing.	(k)(1)(iii) *Revised VAR.* If fish or fish products are landed at a port other than the one specified on the VAR, the vessel operator must submit a revised VAR showing the actual port of landing before any fish are offloaded.

Location § 679.5, paragraph	Current text	Proposed text
(k)(1)(iv)	*Exemption: IFQ departure report.* If a vessel is carrying only IFQ halibut or IFQ sablefish onboard and the operator has submitted a Departure Report per paragraph (1)(5)(iii)(B) of this section, a VAR is not required.	*Exemption: IFQ departure report.* If a vessel is carrying only IFQ halibut or IFQ sablefish onboard and the operator has submitted an IFQ Departure Report per paragraph (1)(4) of this section, a VAR is not required.

Section 679.5(l)(1) IFQ Prior Notice of Landing (PNOL)

The intent of the PNOL is to provide International Pacific Halibut Commission (IPHC) monitoring personnel and OLE personnel advance notice of vessel IFQ landings. Under current regulations, the operator of any vessel intending to make a landing of IFQ halibut, CDQ halibut, or IFQ sablefish must submit a PNOL to OLE 6 hours before making the landing.

This action would revise the PNOL procedure by changing the prior notification from 6 hours to 3 hours. This change would provide adequate monitoring and enforcement opportunities. The 3-hour time limit would result in improved economic efficiency in the fishery, allowing an overall exvessel price for IFQ fish to improve for a vessel operator due to additional time to seek out more competitive marketing opportunities. IFQ card holders and Registered Buyers would have more flexibility during their business negotiations. In general, this action would relieve burdens on small entities, which include Registered Buyers. It may contribute to increased competition in the delivery market for IFQ halibut and sablefish. It could benefit consumers and even cause Registered Buyers to expand into more markets (*i.e.*, fresh fish). The estimated number of directly regulated small entities would include approximately 3,485 holders of halibut QS, 872 holders of sablefish QS, approximately 290 hired masters, and all six of the CDQ groups hold CDQ halibut.

In addition, vessels would be required to report ''location of landings'' rather than ''Registered Buyer.'' This change would provide IPHC and OLE personnel with the exact location of the landing, which is needed to plan monitoring activities, while not requiring a vessel to commit to a specific processor.

Detailed changes to the PNOL regulatory text are presented below:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
(l) heading			X		
Introductory (l)			X		
(l)(1) heading			X		
(l)(1)(i) heading			X		
(l)(1)(i)	(l)(1)(i)(A)		X		
(l)(1)(ii)	(l)(1)(i)(B)		X		
(l)(1)(v)	(l)(1)(ii)		X		
Introductory (l)(1)(iii)			X		
(l)(1)(iii)(A)		X			
(l)(1)(iii)(B), (C)			X		
(l)(1)(iii)(D)		X			
(l)(1)(iii)(E)				X	
(l)(1)(iii)(F) thru (H)	(l)(1)(iii)(E) thru (G)				
(l)(1)(iii)(H)				X	
(l)(1)(iv)			X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.5, paragraph	Current text	Proposed text
(l) heading	IFQ and CDQ halibut recordkeeping and reporting.	IFQ Program recordkeeping and reporting.
Introductory (l)	In addition to the recordkeeping and reporting requirements in this section and as prescribed in the annual management measures published in the FEDERAL REGISTER pursuant to § 300.62 of this title, the following IFQ reports are required, when applicable: prior notices of landing, landing report, shipment report, transshipment authorization, vessel clearance, and IFQ departure report.	In addition to the recordkeeping and reporting requirements in this section and as prescribed in the annual management measures published in the FEDERAL REGISTER pursuant to § 300.62 of this title, the following reports and authorizations are required, when applicable: IFQ Prior Notice of Landing, Product Transfer Report (*see* 679.5(g)), IFQ Landing Report, IFQ Transshipment Authorization, and IFQ Departure Report.
(l)(1) heading	Prior notice of IFQ landing.	IFQ Prior Notice of Landing (PNOL).
(l)(1)(i) heading	Applicability.	Time limits and submittals.
(l)(1)(i)(A)	(l)(1)(i) Except as provided in paragraph (l)(1)(iv) of this section, the operator of any vessel making an IFQ landing must notify OLE, Juneau, AK no fewer than 6 hours before landing IFQ halibut or IFQ sablefish, unless permission to commence an IFQ landing within 6 hours of notification is granted by a clearing officer.	(l)(1)(i)(A) Except as provided in paragraph (l)(1)(iv) of this section, the operator of any vessel making an IFQ landing must notify OLE, Juneau, AK no fewer than 3 hours before landing IFQ halibut or IFQ sablefish, unless permission to commence an IFQ landing within 3 hours of notification is granted by a clearing officer.
(l)(1)(i)(B)	(l)(1)(ii) *Time limits*. A prior notice of landing must be made to the toll-free telephone number 800–304–4846 or to 907–586–7202 between the hours of 0600 hours, A.l.t., and 2400 hours, A.l.t.	(l)(1)(i)(B) A PNOL must be made to the toll-free telephone number 800–304–4846 or to 907–586–7163 between hours of 0600 hours, A.l.t., and the 2400 hours, A.l.t.

Location § 679.5, paragraph	Current text	Proposed text
(l)(1)(ii)	(l)(1)(iii) *Information required*. A prior notice of landing must include the following:	(l)(1)(ii) *Information required*. A PNOL must include the following:
(l)(1)(iii)(B)	Name and permit number of the Registered Buyer who will be responsible for completion and submittal of the IFQ Landing Report(s);	Port of landing and port code from Table 14 to this part;
(l)(1)(iii)(C)	The location of the landing (port name or code).	Exact location of landing within the port, *i.e.*, dock name, harbor name, facility name, or geographical coordinates (latitude and longitude of position in degrees and minutes).
(l)(1)(iv)	(iv) *Exemption.* An IFQ landing of halibut of 500 lb (0.23 mt) or less of IFQ weight determined pursuant to § 679.42(c)(2) and concurrent with a legal landing of salmon or a legal landing of lingcod harvested using dinglebar gear is exempt from the PNOL required by this section.	(iv) *Exemption.* An IFQ landing of halibut of 500 lb or less of IFQ weight determined pursuant to § 679.42(c)(2) and concurrent with a legal landing of salmon or a legal landing of lingcod harvested using dinglebar gear is exempt from the PNOL required by this section.

Section 679.5(l)(2) IFQ Landing Report

Reporting of IFQ harvests is accomplished through electronic submittal of an IFQ Landing Report, which may be submitted by an IFQ cardholder at an automated transaction terminal, through the Internet, and with approval by FAX. A Registered Buyer submits the Landing Report within 6 hours after all fish are landed and prior to shipment or departure of the delivery vessel from the landing site. This action would revise the regulatory text and the procedure for submittal of the IFQ Landing Report for clarity and simplicity. Similar topics are combined under one heading. In some cases, long paragraphs are divided into two paragraphs. Cross references are added to ensure ease of reading. Some telephone numbers are revised. Detailed changes to the regulatory text describing the IFQ Landing Report are presented below:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
Heading for (l)(2)			X		
Heading for (l)(2)(i)			X		
(l)(2)(i)(B)	(l)(2)(i)(A)		X		
New (l)(2)(i)(B)					X
New (l)(2)(i)(C)					X
New (l)(2)(i)(D)					X
New (l)(2)(i)(E)					X
Heading for (l)(2)(iv)	heading for (l)(2)(ii)		X		
(l)(2)(iv)(A)	(l)(2)(ii)(A)		X		
(l)(2)(iv)(B)				X	
(l)(2)(i)(A)	(l)(2)(ii)(B)			X	
(l)(2)(vi)(N)				X	
(l)(2)(vi)	(l)(2)(iii)				
Newly redesignated (l)(2)(iii)(B)			X		
Newly redesignated (l)(2)(iii)(J)			X		
Newly redesignated (l)(2)(iii)(K)			X		
Newly redesignated (l)(2)(iii)(M)			X		
New (l)(2)(iv) and (iv)(A)					X
(l)(2)(ii)(A) except last sentence; last sentence of (l)(2)(ii)(A); (l)(2)(ii)(B).	(l)(2)(iv)(A)		X		
(l)(2)(ii)(D)	(l)(2)(iv)(B)				
(l)(2)(iv)(B) heading					X
(l)(2)(vii); (l)(2)(ii)(E); (l)(2)(iii)(A); (l)(2)(vii)	(l)(2)(iv)(C)		X		
(l)(2)(iv)(D) heading					X
Third sentence of (l)(2)(ii)(C)	(l)(2)(iv)(D)		X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.5, paragraph	Current text	Proposed text
(l)(2) heading	Landing report	IFQ landing report
(l)(2)(i) heading	Applicability	Requirements
(l)(2)(i)(A)	(l)(2)(i)(B) All IFQ catch retained onboard a vessel at commencement of a landing must be weighed and debited from the IFQ permit holder's account under which the catch was harvested.	(l)(2)(i)(A) *All IFQ catch debited.* All IFQ halibut, CDQ halibut, and IFQ sablefish catch must be weighed and debited from the IFQ permit holder's account under which the catch was harvested.
(l)(2)(i)(D)	(l)(2)(ii)(C) Once landing operations have commenced, the IFQ cardholder and the harvesting vessel may not leave the landing site until the IFQ account is properly debited. . . .	(l)(2)(i)(D) *Remain at landing site.* Once landing operations have commenced, the IFQ cardholder and the harvesting vessel may not leave the landing site until the IFQ account is properly debited (as defined in paragraph (l)(2)(iv)(D)).

Location § 679.5, paragraph	Current text	Proposed text
(l)(2)(i)(E)	(l)(2)(ii)(C) . . . The offloaded IFQ species may not be moved from the landing site until the IFQ landing report is received by OLE, Juneau, AK and the IFQ cardholder's account is debited. . . .	(l)(2)(i)(E) *No movement of IFQ species.* The offloaded IFQ species may not be properly moved from the landing site until the IFQ Landing Report is received by OLE, Juneau, AK and the IFQ cardholder's account is properly debited (as defined in paragraph (l)(2)(iv)(D)).
(l)(2)(ii) heading	(l)(2)(iv) *Time limits and submittals*	(l)(2)(ii) *Time limits*
(l)(2)(ii)(A)	(l)(2)(iv)(A) An IFQ landing may commence only between 0600 hours, A.l.t., and 1800 hours, A.l.t., unless permission to land at a different time (waiver) is granted in advance by a clearing officer.	(l)(2)(ii)(A) A landing of IFQ halibut, CDQ halibut, or IFQ sablefish may commence only between 0600 hours, A.l.t., and 1800 hours, A.l.t., unless permission to land at a different time (waiver) is granted in advance by a clearing officer.
(l)(2)(ii)(B)	(l)(2)(i)(A) A Registered Buyer must report an IFQ landing within 6 hours after all such fish are landed and prior to shipment of said fish or departure of the delivery vessel from the landing site.	(l)(2)(ii)(B) A Registered Buyer must submit a completed IFQ Landing Report within 6 hours after all such fish are landed and prior to shipment or transfer of said fish from the landing site.
(l)(2)(iii)(B)	(l)(2)(vi)(B) Location of the IFQ landing (port code or if at sea, lat. and long.)	(l)(2)(iii)(B) Location of the IFQ landing (port code or if at sea, latitude and longitude of position in degrees and minutes).
(l)(2)(iii)(J)	(l)(2)(vi)(J)(*1*) Except as indicated in paragraph (l)(2)(vi)(J)(2) of this section, for each ADF&G statistical area of harvest, the species codes, product codes, and initial accurate scale weight (in pounds or to the nearest thousandth of a metric ton) made at the time of offloading for IFQ species sold and retained. (l)(2)(vi)(J)(*2*) If the vessel operator is a Registered Buyer reporting the IFQ landing, the accurate weight of IFQ sablefish processed product obtained before the offload may be substituted for the initial accurate scale weight at time of offload.	(l)(2)(iii)(J) For each ADF&G statistical area of harvest, the species codes, product codes, and initial accurate scale weight (in pounds or to the nearest thousandth of a metric ton) made at the time of offloading for IFQ species sold and retained. Exception: if the vessel operator is the Registered Buyer reporting the IFQ landing, the accurate weight of IFQ sablefish processed product obtained before the offload may be substituted for the initial accurate scale weight at time of offload.
(l)(2)(iii)(K)	(l)(2)(vi)(K) Whether ice and slime is present on the fish as offloaded from the vessel (YES or NO). Fish which have been washed prior to weighing or which have been offloaded from refrigerated salt water are not eligible for a 2 percent deduction for ice and slime and must indicate NO SLIME & ICE.	(l)(2)(iii)(K) Whether ice and slime are present on the fish as offloaded from the vessel. Fish which have been washed prior to weighing or which have been offloaded from refrigerated salt water are not eligible for a 2 percent deduction for ice and slime and must indicate NO SLIME & ICE.
(l)(2)(iii)(M)	(l)(2)(ii)(C) . . . After the Registered Buyer enters the landing data in the transaction terminal or the Internet submission form(s) and a receipt is printed, the IFQ cardholder must sign the receipt to acknowledge the accuracy of the landing report. . . . (l)(2)(iii)(B) The manual landing report must be signed by the Registered Buyer or his/her representative, and the IFQ cardholder to acknowledge the accuracy of the landing report, and by the OLE representative to show that the IFQ cardholder's account was debited consistent with the landing report. (l)(2)(vi)(M) Signature of Registered Buyer representative. (l)(2)(vi)(N) Signature of IFQ/CDQ cardholder.	(l)(2)(iii)(M) After the Registered Buyer enters the landing data in the transaction terminal or the Internet submission form(s) or submits a manual landing report by FAX, and a receipt is printed, the Registered Buyer or his/her representative, and the IFQ cardholder must sign the receipt(s) to acknowledge the accuracy of the Landing Report.
(l)(2)(iv)(A)	(l)(2)(ii)(A) *Electronic landing report.* (A) Except as indicated in paragraphs (l)(2)(ii)(D) and (E) of this section, electronic landing reports must be submitted to OLE, Juneau, AK using magnetic strip cards issued by NMFS, Alaska Region, and transaction terminals with printers driven by custom-designed software as provided and/or specified by NMFS, Alaska Region. It is the responsibility of the Registered Buyer to locate or procure a transaction terminal and report as required.	(l)(2)(iv)(A) Except as indicated in paragraphs (l)(2)(iv)(B) and (C) of this section, electronic landing reports must be submitted to OLE, Juneau, AK using magnetic strip cards issued by NMFS, Alaska Region, and transaction terminals with printers driven by custom-designed software as provided and/or specified by NMFS, Alaska Region. The Registered Buyer must locate or procure a transaction terminal and report as required.
(l)(2)(iv)(C)	(l)(2)(ii)(E) Waivers from the electronic reporting requirement can only be granted in writing on a case-by-case basis by a local clearing officer (l)(2)(iii)(A) If a waiver has been granted pursuant to paragraph (l)(2)(ii) of this section, manual landing instructions must be obtained from OLE, Juneau, AK at (800) 304–4846. Completed manual landing reports must be submitted by FAX to OLE, Juneau, AK at (907) 586–7313. (l)(2)(vii) *Manual landing report.* When a waiver is issued pursuant to paragraph (l)(2)(ii)(A) of this section, additional information is required. In addition to the information required in paragraph (l)(2)(vi) of this section, the following information is required to complete a landing report using a manual landing report:	(l)(2)(iv)(C) Waivers from the transaction terminal or Internet reporting requirement can only be granted in writing on a case-by-case basis by a local clearing officer. If a waiver is granted, manual landing instructions must be obtained from OLE, Juneau, AK at (800) 304–4846. Registered Buyers must complete and submit manual Landing Reports by FAX to OLE, Juneau, AK at (907)586–7313. When a waiver is issued, the following additional information is required: whether the manual landing report is an original or revised; name, telephone number, and FAX number of individual submitting the manual landing report.

Location § 679.5, paragraph	Current text	Proposed text
(l)(2)(iv)(D)	(l)(2)(ii)(C) . . . A properly concluded transaction terminal receipt, printed Internet submission receipt, or manual landing report receipt received by FAX from OLE, Juneau, AK constitutes confirmation. . . .	(l)(2)(iv)(D) *Properly debited landing.* A properly concluded transaction terminal receipt, printed Internet submission receipt, or manual Landing Report receipt received by FAX from OLE, Juneau, AK, and signed by the OLE representative constitutes confirmation.

Section 679.5(l)(3)

IFQ Shipment Report. This action would remove the requirement for submittal of an IFQ Shipment Report. Currently, an IFQ Shipment Report is used by OLE to monitor and inspect shipments of IFQ halibut, CDQ halibut, and IFQ sablefish to verify proper accounting for fish landings. The Shipment Report documents the first receiver of the IFQ halibut, CDQ halibut or IFQ sablefish. Each Registered Buyer, other than those conducting dockside sales, must complete and submit a written Shipment Report or a bill of lading containing the same information as a Shipment Report for each shipment or transfer of CDQ halibut, IFQ halibut and IFQ sablefish.

Currently, a groundfish PTR is used by OLE to monitor and inspect shipments of groundfish to verify proper accounting for all non-IFQ groundfish landings by documenting the first receiver of the groundfish. Each mothership, catcher/ processor, shoreside processor, or stationary floating processor must complete a written PTR for each shipment or transfer of groundfish.

This action would combine these two forms into one. Under this action, Registered Buyers would submit a PTR for transfer or shipments of all halibut and all sablefish. Groundfish processors would submit a PTR for transfer or shipments of non-IFQ groundfish. If a participant is both a groundfish processor and a Registered Buyer, he or she would submit a PTR for transfer or shipments of non-IFQ groundfish, all halibut and all sablefish. This proposed change would maintain existing data-collection, monitoring, and enforcement capabilities, while reducing the paperwork submittal and storage by the fishing industry.

The specific proposed change to the IFQ Shipment Report regulatory text is presented below: all of § 679.5(l)(3) would be removed, except that some paragraphs are indicated elsewhere as redesignated for inclusion in other sections.

IFQ Dockside Sales Receipt. Regulations pertaining to the IFQ dockside sales receipt would be moved from § 679.5(l)(3)(iv) and placed at § 679.5(l)(5). Regulatory text would be revised by removing ''shipment report'' and adding in its place ''PTR''. The Registered Buyer must issue a dockside sales receipt in lieu of a PTR. No changes in the procedure of issuing a dockside sales receipt would occur as a result of this rule. A person holding a valid IFQ permit, CDQ halibut permit, IFQ card, and Registered Buyer permit may conduct a dockside sale of IFQ halibut or IFQ sablefish to a person who has not been issued a Registered Buyer permit. The purpose of reporting the amount of IFQ fish involved in a dockside sale is to provide OLE with the ability to monitor and inspect the shipment of IFQ fish to determine whether there was proper accounting for all IFQ fish landed.

Section 679.5(l)(4)

IFQ Transshipment Authorization. Regulations pertaining to the IFQ transshipment authorization would be moved from § 679.5(l)(4) and placed at § 679.5(l)(3). No changes in the procedure of transshipment authorization would occur as a result of this rule. Currently, if a person intends to transship processed IFQ halibut, IFQ sablefish, or CDQ halibut between vessels, authorization from a OLE clearing officer to do so must be obtained for each instance of transshipment. The request must be made at least 24 hr before the transshipment is intended to commence.

IFQ Departure Report. Regulations pertaining to the IFQ departure report would be moved from § 679.5(l)(5)(xi) and placed at § 679.5(l)(4). Some of the information originally requested as part of a Vessel Clearance would be added to the IFQ Departure Report. Instead of obtaining an IFQ Vessel Clearance at a principal port prior to departing the waters of the EEZ adjacent to the jurisdictional waters of the State of Alaska, the territorial sea of the State of Alaska, or the internal waters of the State of Alaska, a vessel operator would call OLE by telephone and provide the answers to OLE questions listed on the Departure Report. Detailed changes to the IFQ Departure Report regulatory text are presented below:

§ 679.5, paragraph	Redesignated as	No Change	Revised	Removed	Added
(l)(5)(xi) heading	(l)(4) heading				
(l)(4)(i) heading					X
(l)(4)(i)(A) heading					X
(l)(5)(xi)(A)	(l)(4)(i)(A)		X		
(l)(5)(vii)	(l)(4)(i)(B)		X		
(l)(5)(iii)	(l)(4)(i)(C)		X		
(l)(5)(ix)	(l)(4)(i)(D)		X		
(l)(5)(iv)	(l)(4)(i)(E)		X		
(l)(5)(viii)	(l)(4)(ii)		X		
(l)(5)(viii)(H)	(l)(4)(ii)(A)				
(l)(5)(viii)(B)	(l)(4)(ii)(B)				
(l)(5)(viii)(D)	(l)(4)(ii)(C)		X		
(l)(5)(viii)(C)	(l)(4)(ii)(D)		X		
(l)(5)(viii)(G)	(l)(4)(ii)(E)		X		
(l)(5)(viii)(E)	(l)(4)(ii)(F)		X		
(l)(5)(viii)(F)	(l)(4)(ii)(G)				
(l)(5)(viii)(I)				X	

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

§ 679.5, paragraph	Current text	Proposed text
(l)(4)	(l)(5)(xi) Departure report	(l)(4) Departure report.
(l)(4)(i)(A)	(l)(5)(xi)(A) A vessel operator who intends to obtain a vessel clearance outside the State of Alaska must submit an IFQ departure report, by telephone, to OLE, Juneau, AK at 907–586–7225 or 800–304–4846.	(l)(4)(i)(A) *Time limit and submittal.* A vessel operator who intends to make an IFQ halibut, CDQ halibut or IFQ sablefish landing at any location other than in an IFQ regulatory area or in the State of Alaska must submit an IFQ Departure Report, by telephone, to OLE, Juneau, AK at 800–304–4846 or 907–586–7163 between the hours of 0600 hours, A.l.t., and 2400 hours, A.l.t.
(l)(4)(i)(B)	(l)(5)(vii) *Completion of fishing.* An IFQ vessel operator who obtains an IFQ vessel clearance may only obtain that IFQ vessel clearance after completion of all fishing. If any fishing takes place after issuance of an IFQ vessel clearance, the vessel operator must obtain a new IFQ vessel clearance.	(l)(4)(i)(B) *Completion of fishing.* A vessel operator must submit an IFQ Departure Report after completion of all fishing and prior to departing the waters of the EEZ adjacent to the jurisdictional waters of the State of Alaska, the territorial sea of the State of Alaska, or the internal waters of the State of Alaska when IFQ halibut, CDQ halibut or IFQ sablefish are on board.
(l)(4)(i)(C)	(l)(5)(iii) A vessel operator obtaining an IFQ vessel clearance or submitting a departure report must have a Registered Buyer permit.	(l)(4)(i)(C) *IFQ Registered Buyer permit.* A vessel operator submitting an IFQ Departure Report must have a Registered Buyer permit.
(l)(4)(i)(D)	(ix) *First landing of any species.* A vessel operator must land and report all IFQ species on board at the same time and place as the first landing of any species harvested during an IFQ fishing trip.	(l)(4)(i)(D) *First landing of any species.* A vessel operator submitting an IFQ Departure Report must submit IFQ Landing Reports for all IFQ halibut, CDQ halibut and IFQ sablefish on board at the same time and place as the first landing of any IFQ species.
(l)(4)(i)(E)	(l)(5)(iv) *IFQ permits on board.* A vessel operator obtaining an IFQ vessel clearance must ensure that one or more IFQ cardholders is on board with enough remaining IFQ balance to harvest amounts of IFQ fish equal to or greater than all IFQ halibut and IFQ sablefish on board.	(l)(4)(i)(E) *IFQ permits on board.* A vessel operator submitting an IFQ Departure Report must ensure that one or more IFQ cardholders are on board with enough remaining IFQ balance to harvest amounts of IFQ halibut, CDQ halibut or IFQ sablefish equal to or greater than all IFQ halibut, CDQ halibut and IFQ sablefish on board.
(l)(4)(ii)	(l)(5)(viii) *Required information.* To obtain an IFQ vessel clearance, the vessel operator must provide the following information to the clearing officer:	(l)(4)(ii) *Required information.* When submitting an IFQ Departure Report, the vessel operator must provide the following information:
(l)(4)(ii)(C)	(l)(5)(viii)(D) Vessel operator's IFQ Registered Buyer permit number.	(l)(4)(ii)(C) Vessel operator's name and IFQ Registered Buyer permit number.
(l)(4)(ii)(D)	(l)(5)(viii)(C) Name and permit numbers of IFQ permits used to harvest IFQ species on board.	(l)(4)(ii)(D) Halibut IFQ permit numbers and sablefish IFQ permit numbers of IFQ cardholders on board.
(l)(4)(ii)(E)	(l)(5)(viii)(G) IFQ areas of harvest.	(l)(4)(ii)(E) Halibut Regulatory Areas or Sablefish Regulatory Areas of harvest or both.
(l)(4)(ii)(F)	(l)(5)(viii)(E) Estimated total weight of IFQ halibut on board (1b/kg/mt).	(l)(4)(ii)(F) Estimated total weight of IFQ halibut or CDQ halibut on board (lb/kg/mt).

Section 679.5(l)(5)

IFQ Vessel Clearance. OLE reports that 65 Vessel Clearances were processed in 2001. This indicates that a relatively small number of all vessels making IFQ landings would be directly regulated by this provision. The Vessel Clearance requirement would be replaced with a verbal ''Departure Report'' submitted by telephone prior to leaving the jurisdiction of the Council. This would mean vessels would not have to meet an OLE officer dockside at a Primary Port. A Departure Report would be required for vessels delivering their IFQ fish outside Alaska.

All of paragraph (l)(5) of this section would be removed, except that some paragraphs are indicated elsewhere as redesignated for inclusion in other sections. This action would also amend the FMPs so that the intent of the FMPs incorporates the practical limitations of OLE to meet the requirements of the FMPs. OLE personnel are not currently able to effectively determine catch quantity at the Vessel Clearance port and are unable to seal a vessel's hold without compromising vessel safety.

Landing Verification and Record Retention. In this section, all of the regulatory text regarding landing verification and record retention would be placed under (l)(5).

Section 679.5(l)(6)

Sampling. All of the regulatory text regarding sampling would be placed under (l)(6). Detailed changes are given below:

§ 679.5, paragraph	Redesignated as	No change	Revised	Removed	Added
(l)(5) heading			X		
first sentence of (l)(2)(v)	(l)(5)(i)		X		
(l)(6)	(l)(5)(ii)		X		
(l)(6) heading			X		
First sentence of (l)(2)(v)	(l)(6)(i)		X		
Second sentence of (l)(2)(v)	(l)(6)(ii)		X		

Section 679.7 Prohibitions

This action would amend § 679.7(f)(6) to include the IFQ card requirement for a hired master. In addition, § 679.7(f)(12) would be revised to change the submittal time limit for the PNOL from 6 hours to 3 hours prior notice. Detailed changes are presented below:

§ 679.7, paragraph	Redesignated as	No change	Revised	Removed	Added
(f)(6)			X		
(f)(12)			X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.7, paragraph	Remove . . .	Add
(f)(6)	Make an IFQ halibut, IFQ sablefish, or CDQ halibut landing without an IFQ or CDQ card in the name of the individual making the landing.	*Landing.* (i) *IFQ or CDQ card.* Make an IFQ halibut, IFQ sablefish, or CDQ halibut landing without an IFQ or CDQ card in the name of the individual making the landing. (ii) *Hired master.* Make an IFQ halibut, IFQ sablefish, or CDQ halibut landing without an IFQ or CDQ card listing the name of the hired master and the name of the vessel making the landing.
(f)(12)	Make an IFQ landing without prior notice of landing and before 6 hours after such notice, except as provided in § 679.5.	Make an IFQ landing without a PNOL and before 3 hours after such notice, except as provided in § 679.5

Section 679.32 Groundfish and Halibut CDQ Catch Monitoring

This action would revise the reference in paragraph (f)(2)(iv) of this section to include paragraph (g) of this section for the PTR and paragraph (l) of this section for IFQ R&R. This would be necessary because participants in the CDQ halibut fishery are required to follow the IFQ regulations for R&R given in paragraph (l) of this section and requirements to file the PTR in paragraph (g) of this section.

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.32, paragraph	Remove . . .	Add
(f)(2)(iv)	A person may land halibut CDQ only if he or she has a valid halibut CDQ card, and that person may deliver halibut CDQ only to a person with a valid registered buyer permit. The person holding the halibut CDQ card and the Registered Buyer must comply with the requirements of § 679.51(l)(1) and (l)(2).	A person may land halibut CDQ only if he or she has a valid halibut CDQ card, and that person may deliver halibut CDQ only to a person with a valid registered buyer permit. The person holding the halibut CDQ card and the Registered Buyer must comply with the requirements of § 679.5(g) and (l).

Section 679.42 Limitations on Use of QS and IFQ

This action would correct the regulatory text of § 679.42 by removing incorrect reference to § 679.42(k), by separating the text into numbered subparagraphs, and by correcting the metric ''equivalent'' to 5,000 lb. The amounts described by pounds and metric tons are not equal, and this regulation is stating an exact amount in both pounds and metric tons. Other detailed changes for § 679.42 are presented below:

§ 679.42, paragraph	Redesignated as	No change	Revised	Removed	Added
(a)			X		
(c)(1)(ii)			X		
(c)(1)(iv)			X		
(c)(2)(i)			X		

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Location § 679.42, paragraph	Current text	Proposed text
(a)	The QS or IFQ specified for one IFQ regulatory area must not be used in a different IFQ regulatory area. Except as provided in paragraph (k) of this section or in § 679.41(i)(1) of this part, the IFQ assigned to one vessel category must not be used to harvest IFQ species on a vessel of a different vessel category. Notwithstanding. § 679.40(a)(5)(ii) of this part, IFQ assigned to vessel Category B must not be used on any vessel less than or equal to 60 ft (18.3 m) LOA to harvest IFQ halibut in IFQ regulatory area 2C or IFQ sablefish in the IFQ regulatory area east of 140° W. long. unless such IFQ derives from blocked QS units that result in IFQ of less than 5,000 lb (2.3 mt), based on the 1996 TAC for fixed gear specified for the IFQ halibut fishery and the IFQ sablefish fishery in each of these two regulatory areas.	(1) The QS or IFQ specified for one IFQ regulatory area must not be used in a different IFQ regulatory area. (2) Except as provided in § 679.41(i)(1) of this part, the IFQ assigned to one vessel category must not be used to harvest IFQ species on a vessel of a different vessel category. (3) Notwithstanding § 679.40(a)(5)(ii) of this part, IFQ assigned to vessel Category B must not be used on any vessel less than or equal to 60 ft (18.3 m) LOA to harvest IFQ halibut in IFQ regulatory area 2C or IFQ sablefish in the IFQ regulatory area east of 140° W. long. unless such IFQ derives from blocked QS units that result in IFQ of less than 5,000 lb, based on the 1996 TAC for fixed gear specified for the IFQ halibut fishery and the IFQ sablefish fishery in each of these two regulatory areas.
(c)(1)(ii)	Be aboard the vessel at all times during the fishing operation.	Be aboard the vessel at all times during the fishing trip and present during the landing.
(c)(1)(iv)	Sign the IFQ landing report required by § 679.5(l)(2)(ii)(C) and (iii)(B).	Sign the IFQ Landing Report required by § 679.5(l)(2)(iv)(D).
(c)(2)(i)	Except as provided in § 679.5(l)(2)(vi)(J)(*2*), if offload of unprocessed IFQ halibut, CDQ halibut or IFQ sablefish from a vessel, the scale weight of the halibut or sablefish product actually measured at the time of offload, as required by § 679.5(l)(2)(vi) to be included in the IFQ Landing Report.	Except as provided in § 679.5(l)(2)(iii)(J), if offload of unprocessed IFQ halibut, CDQ halibut or IFQ sablefish from a vessel, the scale weight of the halibut or sablefish product actually measured at the time of offload, as required by § 679.5(l)(2)(iii) to be included in the IFQ Landing Report.

Section 679.43 Determinations and Appeals

In addition to the changes in R&R for groundfish and the IFQ Program, paragraph 679.43(c) would be revised to correct the address for the Office of Administrative Appeals.

Revisions to the regulatory text are presented below, showing the location of the text, the current text, and the proposed text.

Paragraph	Current text	Proposed text
679.43(c)	Appeals must be in writing and must be submitted to the Office of Administrative Appeals, P.O. Box 21668, Juneau, AK 99802 or delivered to: Federal Building, 709 West 9th St., Room 801, Juneau, AK..	Appeals must be in writing and must be mailed to the: National Marine Fisheries Service, Office of Administrative Appeals, P.O. Box 21668, Juneau, AK 99802–1668 or delivered to: National Marine Fisheries Service, Attention: Appeals (OAA) 709 West 9th St., Room 453, Juneau, AK 99801.

Tables

Tables 14a, b, and c to 50 CFR part 679 are revised by removing the coordinates and indications for IFQ primary ports of landing and by indicating ''other'' for each State and Canada. The port of Vancouver, Canada, and code number 803 are added to Table 14b.

Classification

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

This rule does not duplicate, overlap, or conflict with other Federal regulations.

This rule contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA) and which have been approved by OMB. These requirements are listed by OMB control number.

OMB No. 0648–0272. These requirements and their associated burden estimates per response are: 18 minutes for Landing Report and 12 minutes for Transshipment Authorization.

This proposed rule also contains revised requirements that have been submitted to OMB for approval. These requirements are listed by OMB control number.

OMB No. 0648–0213. This requirement and its associated burden estimate per response is: 14 minutes for Vessel Activity Report.

OMB No. 0648–0272. These revised requirements and their associated burden estimates per response are: 12 minutes for IFQ Prior Notice of Landing; 6 minutes for IFQ Departure Report; 6 minutes for IFQ Dockside sales receipt; 18 minutes for Shipment Report are removed; and 12 minutes for Vessel Clearance are removed.

OMB No. 0648–0213. This revised requirement and its associated burden estimate per response is: 20 minutes for Product Transfer Report.

Response times include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; 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, including through the use of automated collection techniques or other forms of information technology.

Send comments on these or any other aspects of the collection of information to NMFS, Alaska Region (see

ADDRESSES), and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer).

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

In general, these actions would improve the efficiency of data collection required under existing IFQ regulations and stem from a joint collaboration of the NOAA Office of Law Enforcement (OLE), Alaska Region, and members of the affected industry. Together, they agreed to changes to the R&R requirements for the IFQ program. These changes were further reviewed by the United States Coast Guard, the Council, and the International Pacific Halibut Commission. An IFQ Implementation Team has recommended adoption of these measures to the Council.

These actions would result in removing the IFQ Shipment Report and IFQ Vessel Clearance. As a consequence of their removal, other forms such as the IFQ Landing Report, IFQ Prior Notice of Landing, IFQ Departure Report, the Product Transfer Report and Vessel Activity Report are proposed to be changed. Definitions for ''authorized officer'', ''clearing officer'' and ''IFQ landing'' would be revised. Overall, these changes will result in improved economic efficiency for the affected fisheries by allowing the vessel operators additional time to find competitive prices at the processors. Furthermore, the action would relieve burdens on small entities, as concluded in the Regulatory Impact Review (RIR), by simplifying, combining and clarifying reporting forms and requirements.

NMFS determined that this proposed rule warrants a Categorical Exclusion from National Environmental Policy Act (NEPA) requirements for an EA. The changes proposed in this action are consistent with the intent and purpose of the Halibut Act with respect to halibut, the Magnuson-Stevens Act with respect to sablefish, and the groundfish FMPs.

These proposed actions—FMP amendments and amendment to regulations promulgated under the Groundfish FMP and Halibut Act—have been evaluated to determine the appropriateness of a Categorical Exclusion for preparation of a NEPA analysis. According to agency NEPA guidance found at NAO 216–6, Section 5.05b, to qualify for a categorical exclusion from NEPA analysis, this agency needs to determine if (1) a prior NEPA analysis for the same action demonstrated that the action will not have significant impacts on the quality of the human environment; or (2) the proposed action is likely to result in significant impacts as defined in 40 CFR 1508.27. Further, according to section 6.02 of NAO 216–6, an action is disqualified from Categorical Exclusions for several reasons, including: (1) The action may be reasonably expected to jeopardize the sustainability of any target or non-target species that may be affected by the action; (2) the action may reasonably be expected to cause substantial damage to the ocean and coastal habitats and/or essential fish habitats defined under the MSA and identified in the FMPs; (3) the action may be reasonably expected to have a substantial adverse impact on public health or safety; (4) the action may be reasonably expected to adversely affect endangered or threatened species, marine mammals, or critical habitat of these species; (5) the action may be reasonably expected to result in cumulative effects that could have a substantial effect on the target species or non-target species; (6) the action may be expected to have a substantial impact on biodiversity and ecosystem function within the affected area; (7) if significant social or economic impacts are interrelated with significant natural or physical environmental effects than an Environmental Impact Statement (EIS) should discuss all the effects on the human environment; and (8) the degree to which the effects on the quality of the human environment are likely to be highly controversial.

For the following reasons, and in consideration of guidance under NAO 216–6, the prior NEPA analyses—the SEIS for Groundfish of the GOA and the SEIS for the Halibut IFQ program—provide sufficient analysis of the direct, indirect and cumulative impacts of the recordkeeping and reporting component to the IFQ fisheries affected here. Further, none of the considerations under section 6.02 exist here given: (1) The nature of the action and its goals, that is that the action is a refinement of recordkeeping and reporting and seeks to reduce the time required for complying with such; and (2) that the action will reduce the window of time required for vessels to alert the agency that they will be offloading catch at processors.

As determined in the accompanying RIR and IRFA analyses, conservation and management goals will be unaffected by the actions. The actions will not affect public health and safety and are not controversial. Because the actions do not alter fishing but rather landings and reporting, the actions will not affect the target or non-target species that are caught pursuant to the IFQ programs affected here. The actions do not establish any precedent or decision in principle about future proposals or result in cumulatively significant impacts nor have any adverse impacts on endangered or threatened species or their habitats.

In conclusion, these actions would improve the efficiency of data collection required under existing IFQ regulations and would implement those recommendations received from industry, enforcement and management. Based on the foregoing conclusions, these revisions to recordkeeping and reporting for the IFQ fisheries would not substantively alter environmental impacts already analyzed within existing environmental documents.

NMFS prepared an initial regulatory flexibility analysis that describes the impact this proposed rule, if adopted, would have on small entities.

The legislative authority for these actions is the Magnuson-Stevens Fishery Conservation and Management Act, Public Law (Pub. L.) 94–265, 16 U.S.C. 1801 (Magnuson-Stevens Act), and the Northern Pacific Halibut Act of 1982 (NPHA) Public Law 97–176, 16 U.S.C. 773 c (c).

Action 1

Under current regulations, operators of vessels making halibut or sablefish IFQ landings must notify the NOAA Fisheries Office for Law Enforcement six hours before the landing and must include the name of the Registered Buyer to whom they are delivering the IFQ fish. These regulations have been found to put IFQ fishermen at a disadvantage in their negotiations with Registered Buyers, to make it more difficult for Registered Buyers to market fresh product, and to reduce the ability of IFQ fishermen to respond to changing business conditions. The preferred alternative for this action would address these problems by reducing the notification time from six hours to three, and by eliminating the requirement that persons landing IFQ fish include the name of the Registered Buyer in the notification. Persons landing IFQ fish only would have to include the location of the landing in the notification.

The maximum number of directly regulated small entities would be approximately 3,485 holders of halibut QS, and 872 holders of sablefish QS. In addition, all six of the CDQ groups hold

CDQ halibut QS and would be directly regulated. A total of 270 individual fishermen landed CDQ halibut in 2001 and may be directly regulated by this regulatory change. NMFS/RAM issued 694 permits for Registered Buyers in 2001, and, of these, 215 reported landings. Registered Buyers also would be directly regulated by this change.

In general, this proposed rule would relieve burdens on small entities, especially vessel owners of IFQ's. Proposed changes may contribute to increased competition in the delivery market for IFQ halibut and sablefish and thus may have some adverse impact on less economically efficient Registered Buyers. There are no data available on whether or not this impact will occur, or on how serious it may be.

This action does not impose new record keeping requirements or duplicate, overlap or conflict with other Federal rules. NMFS considered an alternative to totally eliminate the prior notice of landing requirement. This might have relieved more of the burden on small entities (although it might still have adversely impacted less efficient Registered Buyers). However, this alternative would have adversely affected data-collection, monitoring, and enforcement operations. NMFS also considered an alternative to randomly apply the prior notice requirements to vessels. Under this system, some vessels would be relieved of a prior notice burden, but all vessels would have been subjected to additional ''hail-out'' reporting burdens when they put to sea. Port-sampling might be adversely impacted, with biases introduced into sampling methods that might affect the quality of data used in stock assessments. Therefore, neither of these alternatives was chosen as the preferred alternative.

Action 2

At the present time, vessels may only begin to land IFQ catch between 6 a.m. and 6 p.m. (the ''offload window''). Industry has expressed an interest in extending the offload window later in the evening. However, industry has also indicated that if the preferred alternative in Action 1 were taken, the flexibility provided would make it unnecessary to extend the window. The preferred alternative, therefore, is continuation of the status quo.

The maximum number of affected small entities would be the approximately 3,485 persons (individuals, corporations, and other entities) who held halibut QS; 872 persons held sablefish QS. In addition, all six of the CDQ groups that hold CDQ halibut would be affected. A total of 270 individuals landed CDQ halibut in 2001 and may be affected by this regulation. NMFS/RAM issued 694 permits for Registered Buyers in 2001, and, of these, 215 reported landings. Registered Buyers also would be affected by this change in regulation.

This action does not appear to have an adverse impact on small entities. This action does not impose new record keeping requirements or duplicate, overlap, or conflict with other Federal rules.

Action 3

The preferred alternative for this action eliminates the requirement for vessels to pull into port to obtain a vessel clearance prior to leaving the EEZ off Alaska. IFQ permit holders state that the requirement is onerous and costly when they have to divert to come dockside for a clearance. They also say there are not enough port options for obtaining clearance in a timely fashion. The objective of this action is to reduce the burden on fishermen by substituting a verbal ''departure report'' for the currently-required vessel clearance. A verbal report would not diminish the ability to monitor and enforce catch reporting/quota requirements on vessels leaving the jurisdiction of the Council since other reporting mechanisms are available in the port of delivery to monitor those vessels.

As proposed, this preferred alternative for Action 3 would directly regulate the 1,451 unique vessels which made IFQ halibut landings, and 433 unique vessels which made sablefish landings in 2001. OLE reports that 65 vessel clearances were processed in 2001. This indicates that a relatively small number of all vessels making IFQ landings would be directly regulated by this provision, because to obtain the highest quality product, vessels generally offload halibut as soon as possible at a port of Alaska.

NMFS has not identified any adverse impacts to small entities from this action. It does not impose new record keeping requirements or duplicate, overlap or conflict with other federal rules. NMFS is not aware of any alternatives in addition to the alternatives considered that would accomplish the objectives of the Magnuson-Stevens Act and other applicable statutes and that would minimize the economic impact of the proposed rule on small entities.

Action 4

Regulations currently require that Registered Buyers of IFQ sablefish and halibut and CDQ sablefish report landings on a shipment report. Processors are required to report groundfish landings on a separate product transfer report (PTR). Those processors that are also Registered Buyers must submit a PTR for groundfish and a shipment report for IFQ halibut and sablefish and for CDQ halibut. The IFQ fishing industry has expressed concern that this report is duplicative. The purpose of this action is to improve the transfer procedure paperwork and to eliminate some occurrence of duplication. For example under current regulations, an offload of IFQ halibut or sablefish generally also includes incidental groundfish harvest. A PTR is created for the incidental groundfish; a shipment report is created for the IFQ halibut or sablefish. In other words, two pieces of paper document one offload. With the proposed combination of the IFQ shipment report and the groundfish product transfer report, both the IFQ fish and the incidental groundfish would be reported on one document.

As proposed, the preferred alternative for action 4 would directly regulate Registered Buyers, all of whom are assumed to be ''small business,'' based upon RFA criteria. NMFS/RAM issued 694 permits for Registered Buyers in 2001, and, of these, 215 reported landings. Therefore, some multiple of 215 shipment reports and an estimated two-thirds of these, or 144 PTRs, were submitted by Registered Buyers in 2001. The proposed change would eliminate the 144 PTRs.

This action would impose no adverse impacts on small entities, and it does not appear to impose new record keeping requirements or duplicate, overlap, or conflict with other Federal rules.

A copy of this analysis is available from NMFS (see **ADDRESSES**).

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Recordkeeping and reporting requirements.

Dated: January 6, 2003.

Rebecca Lent,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR part 679 is proposed to be amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

2. In § 679.2, revise in alphabetical order the definitions for ''Authorized officer,'' ''Clearing officer,'' ''IFQ landing,'' ''IFQ Permit Holder,'' ''IFQ Registered Buyer,'' and ''Transfer'' to read as follows:

§ 679.2 Definitions.

Authorized officer means:

(1) Any commissioned, warrant, or petty officer of the USCG;

(2) Any special agent or fishery enforcement officer of NMFS;

(3) Any officer designated by the head of any Federal or state agency that has entered into an agreement with the Secretary and the Commandant of the USCG to enforce the provisions of the Magnuson-Stevens Act or any other statute administered by NOAA; or

(4) Any USCG personnel accompanying and acting under the direction of any person described in paragraph (1) of this definition.

* * * * *

Clearing officer means, a NOAA Fisheries Office for Law Enforcement (OLE) special agent, an OLE fishery enforcement officer, or an OLE enforcement aide.

* * * * *

IFQ landing means, the unloading or transferring of any IFQ halibut, CDQ halibut, IFQ sablefish, or products thereof from the vessel that harvested such fish or the removal from the water of a vessel containing IFQ halibut, CDQ halibut, IFQ sablefish, or products thereof.

IFQ permit holder means the person identified on an IFQ permit, at the time a landing is made, as defined at § 679.4(d)(1).

* * * * *

IFQ registered buyer means the person identified on a Registered Buyer permit, as defined at § 679.4(d)(3).

* * * * *

Transfer means:

(1) *Groundfish fisheries of the GOA and BSAI.* Any loading, offloading, shipment or receipt of any groundfish product by a mothership, catcher/processor, shoreside processor, or stationary floating processor, including quantities transferred inside or outside the EEZ, within any state's territorial waters, within the internal waters of any state, at any shoreside processor, stationary floating processor, or at any offsite meal reduction plant.

(2) *IFQ halibut, CDQ halibut, IFQ sablefish.* Any loading, offloading, shipment or receipt of any IFQ halibut, CDQ halibut, IFQ sablefish product, including quantities transferred inside or outside the EEZ, within any state's territorial waters, within the internal waters of any state, at any shoreside processor, stationary floating processor, or at any offsite meal reduction plant.

* * * * *

3. In § 679.4, paragraph (d) is revised to read as follows:

§ 679.4 Permits.

* * * * *

(d) *IFQ permits, IFQ cards, and IFQ Registered Buyer permits.* The permits and cards described in this section are required in addition to the permit and licensing requirements prescribed in the annual management measures published in the **Federal Register** pursuant to § 300.62 of chapter III of this title and in the permit requirements of this section.

(1) *IFQ permit.* (i) An IFQ permit authorizes the person identified on the permit to harvest IFQ halibut or IFQ sablefish from a specified IFQ regulatory area at any time during an open fishing season during the fishing year for which the IFQ permit is issued until the amount harvested is equal to the amount specified under the permit, or until it is revoked, suspended, or modified under 15 CFR part 904.

(ii) A legible copy of any IFQ permit that specifies the IFQ regulatory area and vessel length overall from which IFQ halibut or IFQ sablefish may be harvested by the IFQ permit holder must be carried on board the vessel used by the permitted person to harvest IFQ halibut or IFQ sablefish at all times that such fish are retained on board.

(2) *IFQ card.* (i) An IFQ card authorizes the individual identified on the card to land IFQ halibut or IFQ sablefish for debit against the specified IFQ permit until the card expires, or is revoked, suspended, or modified under 15 CFR part 904, or cancelled on request of the IFQ permit holder.

(ii) An original IFQ card issued by the Regional Administrator must be on board the vessel that harvests IFQ halibut or IFQ sablefish at all times that such fish are retained on board. Except as specified in § 679.42(d), an individual that is issued an IFQ card must remain aboard the vessel used to harvest IFQ halibut or IFQ sablefish with that card during the IFQ fishing trip and at the landing site during all IFQ landings.

(iii) Each IFQ card issued by the Regional Administrator will display an IFQ permit number, the name of the individual authorized by the IFQ permit holder to land IFQ halibut or IFQ sablefish for debit against the permit holder's IFQ. In addition, IFQ cards issued to hired masters representing permit holders per § 679.42(i) and (j) will also display the ADF&G vessel identification number of the authorized vessel.

(3) *Registered Buyer permit.* (i) A Registered Buyer permit authorizes the person identified on the permit to receive and make an IFQ landing by an IFQ permit or card holder at any time during the fishing year for which it is issued until the Registered Buyer permit expires, or is revoked, suspended, or modified under 15 CFR part 904.

(ii) A Registered Buyer permit is required of:

(A) Any person who receives IFQ halibut, CDQ halibut or IFQ sablefish from the person(s) who harvested the fish;

(B) Any person who harvests IFQ halibut or IFQ sablefish and transfers such fish in a dockside sale, outside of an IFQ regulatory area, or outside the State of Alaska.

(C) A vessel operator who submits a Departure Report (*see* § 679.5(l)(4))

(iii) A Registered Buyer permit is issued on a 3-year cycle by the Regional Administrator to persons that have a Registered Buyer application approved by the Regional Administrator.

(iv) A Registered Buyer permit is in effect from the date of issuance through the end of the current NMFS 3-year cycle, unless it is revoked, suspended, or modified under § 600.735 or § 600.740 of this chapter.

(4) *Issuance.* The Regional Administrator will renew IFQ permits and cards annually or at other times as needed to accommodate transfers, revocations, appeals resolution, and other changes in QS or IFQ holdings, and designation of masters under § 679.42.

(5) *Transfer.* The quota shares and IFQ issued under this section are not transferable, except as provided under § 679.41. IFQ cards and Registered Buyer permits issued under this paragraph (d) are not transferable.

(6) *Inspection.* (i) *IFQ permit and card.* The IFQ cardholder must present a copy of the IFQ permit and the original IFQ card for inspection on request of any authorized officer or Registered Buyer receiving IFQ species. Nothing in this paragraph would prevent an individual who is issued an IFQ card from being absent from the vessel used to harvest IFQ halibut or IFQ sablefish from the time the vessel arrives at the point of landing and the commencement of landing.

(ii) *Registered Buyer permit.* A legible copy of the Registered Buyer permit must be present at the location of an IFQ landing and must be made available by the Registered Buyer's representative for inspection on request of any authorized officer.

(7) *Validity.* An IFQ permit issued under this part is valid only if all IFQ fee liability of the IFQ permit holder that is due as a result of final agency action has been paid as specified in §§ 679.45 and 679.5(l)(7)(ii).

* * * * *

4. In § 679.5, paragraphs (a)(1)(ii)(A) and (B), (a)(15), (g), (k), and (l) are revised to read as follows:

§ 679.5 Recordkeeping and reporting.

(a) * * *

(1) * * *

(ii) * * *

(A) *Groundfish received.* A shoreside processor, stationary floating processor, mothership, or buying station subject to recordkeeping and reporting requirements must report all groundfish and prohibited species received, including fish received from vessels not required to have a federal fisheries permit; and fish received under contract for handling or processing for another processor.

(B) *Groundfish transferred.* A shoreside processor, stationary floating processor, or mothership subject to recordkeeping and reporting requirements must report all groundfish and prohibited species transferred out of the facility or off the vessel.

* * * * *

(15) *IFQ/groundfish transfer comparison.* The operator, manager, or Registered Buyer may refer to the following table for submittal, issuance, and possession requirements for each type of IFQ or non-IFQ groundfish transfer activity. The locations of the paragraphs that describe the requirements of each activity are also given.

	Submittal			Issue		Possess
	VAR	PTR	IFQ Trans-shipment Author-ization	IFQ De-parture Report	IFQ Dockside Sale Re-ceipt	IFQ Landing Report Receipt
(i) If a catcher vessel, mothership or catcher/processor leaving or entering Alaska with non-IFQ groundfish and no IFQ product onboard (*see* § 679.5(k)))	X	.....	.....	.....	.....	.....
(ii) If a vessel leaving Alaska with IFQ sablefish or IFQ halibut but no other non-IFQ groundfish onboard (*see* § 679.5(l)(4))	.....	.....	.....	X	.....	.....
(iii) If a vessel leaving Alaska with IFQ sablefish or IFQ halibut and other non-IFQ groundfish onboard (*see* § 679.5(k) and 679.5(l)(4))	X	.....	.....	X	.....	.....
(iv) Transfer of non-IFQ groundfish (*see* § 679.5(g))	.....	X	.....	.....	.....	.....
(v) Transfer of IFQ species from an IFQ Registered Buyer (*see* § 679.5(g))	.....	X	.....	.....	.....	.....
(vi) Transfer of IFQ species from IFQ Cardholder with a IFQ Registered Buyer permit in a dockside sale (*see* § 679.5(l)(5))	.....	.....	.....	.....	XXX	.....
(vii) Transfer of IFQ species from landing site to IFQ Registered Buyer's processing facility (*see* § 679.5(g)(1)(vi))	.....	.....	.....	.....	.....	XX
(viii) Transfer of IFQ processed product between vessels (*see* § 679.5(l)(3))	.....	.....	XXXX	.....	.....	.....

X Indicates under what circumstances each report is submitted;
XX Indicates that the document must accompany the transfer of IFQ species from landing site to processor;
XXX Indicates receipt must be issued to each receiver in a dockside sale;
XXXX Indicates authorization must be obtained.

* * * * *

(g) *Product Transfer Report (PTR).* (1) *General Requirements.* Except as provided in paragraphs (g)(1)(i) through (vi) of this section, the operator of a mothership or catcher/processor, the manager of a shoreside processor or stationary floating processor must complete and submit a separate PTR for each transfer (shipment or receipt) of groundfish and donated prohibited species caught in groundfish fisheries. In addition, IFQ Registered Buyers must submit a separate PTR for each transfer (shipment only) of halibut or sablefish for which the Registered Buyer submitted an IFQ or CDQ Landing Report or was required to submit an IFQ or CDQ Landing Report. A PTR is not required to accompany a shipment or transfer.

(i) *Exemption: Bait sales (non-IFQ groundfish only).* The operator or manager may aggregate individual sales or transfers of non-IFQ groundfish to vessels for bait purposes during a day onto one PTR when recording the amount of such bait product leaving a facility that day.

(ii) *Exemption: Retail sales.* For retail sales destined for human consumption and weighing less than 10 lb or 4.5 kilograms, the operator, manager, or IFQ Registered Buyer may aggregate and record on one PTR, the amount of such retail product transferred during one calendar day.

(iii) *Exemption: Wholesale sales (non-IFQ groundfish only).* The operator or manager may aggregate and record on one PTR, wholesale sales of non-IFQ groundfish by species when recording the amount of such wholesale species leaving a facility in one calendar day, if invoices detailing destinations for all of the product are available for inspection by an authorized officer.

(iv) *Exemption: IFQ Registered Buyers.* IFQ Registered Buyers are not required to submit a PTR for ''receipt'' of IFQ halibut, CDQ halibut, or IFQ sablefish.

(v) *Exemption: Dockside sales (IFQ only).* (A) A person holding a valid IFQ permit, IFQ card, and IFQ Registered Buyer permit may conduct a dockside sale of IFQ halibut or IFQ sablefish to a person who has not been issued an IFQ Registered Buyer permit.

(B) An IFQ Registered Buyer conducting dockside sales must issue a receipt to each individual receiving IFQ halibut or IFQ sablefish in lieu of a PTR. This receipt must include the date of sale or transfer, the IFQ Registered Buyer permit number, and the weight by product of the IFQ sablefish or IFQ halibut transferred.

(vi) *Exemption: transfer directly from the landing site to a processing facility (IFQ only).* A PTR is not required for transportation of unprocessed IFQ species directly from the landing site to a processing facility for processing the IFQ species, provided the following conditions are met:

(A) A copy of the IFQ Landing Report receipt (Internet or transaction terminal

receipt) documenting the IFQ landing accompanies the offloaded IFQ species while in transit.

(B) A copy of the IFQ Landing Report receipt is available for inspection by an authorized officer.

(C) For IFQ species transported in this manner, the IFQ Registered Buyer submitting the IFQ Landing Report must still complete a PTR for each transfer of IFQ halibut and IFQ sablefish from the processing facility.

(2) *Time limits and submittal.* The operator of a mothership or catcher/processor, an IFQ Registered Buyer, or manager of a shoreside processor or stationary floating processor must:

(i) *Record on PTR.* Record all product transfer information on a PTR within 2 hours of the completion of the transfer.

(ii) *Submit original PTR.* Submit by FAX or electronic file a copy of each PTR to OLE, Juneau, AK (907–586–7313), by 1200 hours, A.l.t., on the Tuesday following the end of the applicable weekly reporting period in which the transfer occurred.

(iii) *Submit revised PTR.* Ensure that, if any information on the original PTR changes prior to the first destination of the shipment, a revised PTR is submitted by FAX or electronic file to OLE, Juneau, AK (907–586–7313), by 1200 hours, A.l.t., on the Tuesday following the end of the applicable weekly reporting period in which the change occurred.

(3) *General information.* The operator, manager, or IFQ Registered Buyer must record on a PTR:

(i) Whether original or revised PTR;

(ii) Whether you are the shipper or receiver;

(iii) Whether the shipment or receipt is for any combination of non-IFQ groundfish, IFQ products, or CDQ halibut products and record information for each product transferred per paragraph 679.5(g)(4) through (7). If shipment consists of donated prohibited species caught while participating in groundfish fisheries, mark the box ''groundfish.''

(4) *Receiver information.* If documenting receipt of non-IFQ groundfish, the operator or manager must check ''Receiver'; enter your representative's name, telephone number, and FAX number; start and finish date and time of product transfer, position of product transfer (if applicable), port or location of transfer and:

Enter under ''Receiver''	Enter under ''Shipper''
Your processor's name and Federal fisheries or Federal processor permit.	Other processor's name, and Federal fisheries or Federal processor permit (if applicable).

(5)(i) *Shipper Information.* If documenting transfer of product away from your facility or transfer of product off of your vessel, the operator, manager, or IFQ Registered Buyer must enter your representative's name, telephone number, and FAX number, check ''Shipper'' and:

If you are shipping	Enter under ''Shipper''
(A) Non-IFQ groundfish	Your processor's name, Federal fisheries or Federal processor permit number.
(B) IFQ halibut, CDQ halibut or IFQ sablefish	IFQ Registered Buyer name and permit number.
(C) Both non-IFQ groundfish and IFQ halibut, CDQ halibut or IFQ sablefish on the same PTR.	Your processor's name and Federal fisheries permit number or Federal processor permit number; or your IFQ Registered Buyer's name and permit number.

(ii) Using descriptions from the following table, enter receiver information, date and time of product transfer, location of product transfer *e.g.*, port, position coordinates, or city), mode of transportation, and intended route.

If you are the shipper and ...	Then enter ...			
	Receiver	Date & Time of Product Transfer	Location of Product Transfer	Mode of Transportation & Intended Route
(A) Receiver is on land and transfer involves one van, truck, or vehicle.	Receiver name and Federal fisheries or Federal processor permit number (if any).	Date and time when shipment leaves the plant.	Port or city of product transfer.	Name of the shipping company; destination city and state or foreign country.
(B) Receiver is on land and transfer involves multiple vans or trucks.	Receiver name and Federal fisheries or Federal processor permit number (if any).	Date and time when loading of vans or trucks is completed each day.	Port or city of product transfer.	Name of the shipping company; destination city and state or foreign country.
(C) Receiver is on land and transfer involves one airline flight.	Receiver name and Federal fisheries or Federal processor permit number (if any).	Date and time when shipment leaves the plant.	Port or city of product transfer.	Name of the airline company; destination airport city and state.
(D) Receiver is on land and transfer involves multiple airline flights.	Receiver name and Federal fisheries or Federal processor permit number (if any).	Date and time of shipment when the last airline flight of the day leaves.	Port or city of product transfer.	Name of the airline company(s); destination airport(s) city and state.
(E) Receiver is a vessel and transfer occurs at sea.	Vessel name and call sign	Start and finish dates and times of transfer.	Transfer position coordinates in latitude and longitude, in degrees and minutes.	The first destination of the vessel.

If you are the shipper and ...	Then enter ...			
	Receiver	Date & Time of Product Transfer	Location of Product Transfer	Mode of Transportation & Intended Route
(F) Receiver is a vessel and transfer takes place in port.	Vessel name and call sign	Start and finish dates and times of transfer.	Port or position of product transfer.	The first destination of the vessel.
(G) Receiver is an agent (buyer, distributor, or shipping agent) and transfer is in a containerized van.	Agent name and location (city, state).	Transfer start and finish dates and times.	Port, city, or position of product transfer.	Name (if available) of the vessel transporting the van; destination port.
(H) You are aggregating individual retail sales for human consumption in quantities less than 10 lb (0.0045 mt) per sale during a day onto one PTR.	''RETAIL SALES''	Time of the first sale of the day; time of the last sale of the day.	Port or city of product transfer.	n/a.
(I) You are aggregating individual bait sales during a day onto one PTR (non-IFQ groundfish only).	''BAIT SALES''	Time of the first sale of the day; time of the last sale of the day.	Port or city of product transfer.	n/a/.
(J) *Non-IFQ Groundfish only.* You are aggregating wholesale non-IFQ groundfish product sales by species during a single day onto one PTR and maintaining invoices detailing destinations for all of the product for inspection by an authorized officer.	''WHOLESALE SALES'' ...	Time of the first sale of the day; time of the last sale of the day.	Port or city of product transfer.	n/a.

(6) *Products shipped or received.* The operator, manager, or IFQ Registered Buyer must record the following information for each product transferred:

(i) *Species code and product code.* The species code and product code (Tables 1 and 2 to this part).

(ii) *Species weight.* Use only if recording two or more species with one or more product types contained within the same production unit. Enter the actual scale weight of each product of each species to the nearest kilogram or pound (indicate which). If not applicable, enter ''n/a'' in the species weight column. If using more than one line to record species in one carton, use a brace ''}'' to tie the carton information together.

(iii) *Number of units.* Total number of production units (blocks, trays, pans, individual fish, boxes, or cartons; if iced, enter number of totes or containers).

(iv) *Unit weight.* Unit weight (average weight of single production unit as listed in ''No. of Units'' less packing materials) for each species and product code in kilograms or pounds (indicate which).

(v) *Total weight.* Total weight for each species and product code of shipment less packing materials in kilograms or pounds (indicate which).

(7) *Total or partial offload.* (i) If a mothership or catcher/processor, the operator must indicate whether the transfer is a total or partial offload.

(ii) If a partial offload, for the products remaining on board after the transfer, the operator must enter: species code, product code, and total product weight to the nearest kilogram or pound (indicate which) for each product.

* * * * *

(k) *U.S. Vessel Activity Report (VAR)*—(1) *Who needs to submit a VAR?*—(i) *Fish or fish product onboard.* Except as noted in paragraph (k)(1)(iv) of this section, the operator of a catcher vessel greater than 60 ft (18.3 m) LOA, a catcher/processor, or a mothership required to hold a Federal fisheries permit issued under this part and carrying fish or fish product onboard must complete and submit a VAR by FAX or electronic file to OLE, Juneau, AK (907–586–7313) before the vessel crosses the seaward boundary of the EEZ off Alaska or crosses the U.S.-Canadian international boundary between Alaska and British Columbia.

(ii) *Combination of non-IFQ groundfish, IFQ halibut, CDQ halibut, and IFQ sablefish.* If a vessel is carrying non-IFQ groundfish and IFQ halibut, CDQ halibut or IFQ sablefish, the operator must submit a VAR in addition to an IFQ Departure Report per paragraph (l)(4) of this section.

(iii) *Revised VAR.* If fish or fish products are landed at a port other than the one specified on the VAR, the vessel operator must submit a revised VAR showing the actual port of landing before any fish are offloaded.

(iv) *Exemption: IFQ Departure Report.* If a vessel is carrying only IFQ halibut, CDQ halibut, or IFQ sablefish onboard and the operator has submitted an IFQ Departure Report per paragraph (l)(4) of this section, a VAR is not required.

(2) *Information required.* Whether original or revised VAR; name and Federal fisheries permit number of vessel; type of vessel (whether catcher vessel, catcher/processor, or mothership); and representative information (see paragraph (b)(2) of this section).

(i) *Return report.* ''Return,'' for purposes of this paragraph, means returning to Alaska. If the vessel is crossing into the seaward boundary of the EEZ off Alaska or crossing the U.S.-Canadian international boundary between Alaska and British Columbia into U.S. waters, indicate a ''return'' report and enter:

(A) Intended Alaska port of landing (see Table 14 to this part);

(B) Estimated date and time (hour and minute, Greenwich mean time) the vessel will cross;

(C) The estimated position coordinates the vessel will cross.

(ii) *Depart report.* ''Depart'' means leaving Alaska. If the vessel is crossing out of the seaward boundary of the EEZ off Alaska or crossing the U.S.-Canadian international boundary between Alaska and British Columbia into Canadian waters, indicate a ''depart'' report and enter:

(A) The intended U.S. port of landing or country other than the United States;

(B) Estimated date and time (hour and minute, Greenwich mean time) the vessel will cross;

(C) The estimated position coordinates in latitude and longitude the vessel will cross.

(iii) *The Russian Zone.* Indicate whether your vessel is returning from fishing in the Russian Zone or is departing to fish in the Russian Zone.

(iv) *Fish or fish products.* For all fish or fish products (including non-groundfish) on board the vessel, enter: Harvest zone code; species codes; product codes; and total fish product weight in lbs or to the nearest 0.001 mt.

(l) *IFQ halibut, CDQ halibut or IFQ sablefish recordkeeping and reporting.* In addition to the recordkeeping and reporting requirements in this section and as prescribed in the annual management measures published in the **Federal Register** pursuant to § 300.62 of this title, the following reports and authorizations are required, when applicable: IFQ Prior Notice of Landing, Product Transfer Report (*see* § 679.5(g) of this section), IFQ Landing Report, IFQ Transshipment Authorization, and IFQ Departure Report.

(1) *IFQ Prior Notice of Landing (PNOL)*—(i) *Time limits and submittal.* (A) Except as provided in paragraph (l)(1)(iv) of this section, the operator of any vessel making an IFQ landing must notify OLE, Juneau, AK, no fewer than 3 hours before landing IFQ halibut or IFQ sablefish, unless permission to commence an IFQ landing within 3 hours of notification is granted by a clearing officer.

(B) A PNOL must be made to the toll-free telephone number 800–304–4846 or to 907–586–7163 between the hours of 0600 hours, A.l.t., and 2400 hours, A.l.t.

(ii) *Revision to PNOL.* The operator of any vessel wishing to land IFQ halibut or IFQ sablefish before the date and time (A.l.t.) reported in the PNOL or later than 2 hours after the date and time (A.l.t.) reported in the PNOL must submit a new PNOL as described in paragraphs (l)(1)(i) and (iii) of this section.

(iii) *Information required.* A PNOL must include the following:

(A) Vessel name and ADF&G vessel registration number;

(B) Port of landing and port code from Table 14 to this part;

(C) Exact location of landing within the port (*i.e.*, dock name, harbor name, facility name, or geographical coordinates);

(D) The date and time (A.l.t.) that the landing will take place;

(E) Species and estimated weight (in pounds) of the IFQ halibut or IFQ sablefish that will be landed;

(F) IFQ regulatory area(s) in which the IFQ halibut or IFQ sablefish were harvested; and

(G) IFQ permit number(s) that will be used to land the IFQ halibut or IFQ sablefish and Registered Buyer name.

(iv) *Exemption.* An IFQ landing of halibut of 500 lb or less of IFQ weight determined pursuant to § 679.42(c)(2) and concurrent with a legal landing of salmon or a legal landing of lingcod harvested using dinglebar gear is exempt from the PNOL required by this section.

(2) *IFQ landing report*—(i) *Requirements*—(A) *All IFQ catch debited.* All IFQ halibut, CDQ halibut, and IFQ sablefish catch must be weighed and debited from the IFQ permit holder's account under which the catch was harvested.

(B) *Single offload site for halibut.* The vessel operator who lands IFQ halibut or CDQ halibut must continuously and completely offload at a single offload site all halibut on board the vessel.

(C) *Single offload site for sablefish.* The vessel operator who lands IFQ sablefish must continuously and completely offload at a single offload site all sablefish on board the vessel.

(D) *Remain at landing site.* Once landing operations have commenced, the IFQ cardholder and the harvesting vessel may not leave the landing site until the IFQ account is properly debited (as defined in paragraph (l)(2)(iv)(D) of this section).

(E) *No movement of IFQ halibut, CDQ halibut, or IFQ sablefish.* The offloaded IFQ halibut, CDQ halibut, or IFQ sablefish may not be moved from the landing site until the IFQ Landing Report is received by OLE, Juneau, AK, and the IFQ cardholder's account is properly debited (as defined in paragraph (l)(2)(iv)(D) of this section).

(ii) *Time limits.* (A) A landing of IFQ halibut, CDQ halibut, or IFQ sablefish may commence only between 0600 hours, A.l.t., and 1800 hours, A.l.t., unless permission to land at a different time (waiver) is granted in advance by a clearing officer.

(B) A Registered Buyer must submit a completed IFQ Landing Report within 6 hours after all IFQ halibut, CDQ halibut, or IFQ sablefish are landed and prior to shipment or transfer of said fish from the landing site.

(iii) *Information required.* The Registered Buyer must enter accurate information contained in a complete IFQ Landing Report as follows:

(A) Date and time (A.l.t.) of the IFQ landing;

(B) Location of the IFQ landing (port code or if at sea, lat. and long.);

(C) Name and permit number of the IFQ card holder;

(D) Name and permit number of Registered Buyer receiving the IFQ species;

(E) The harvesting vessel's name and ADF&G vessel registration number;

(F) Gear type used to harvest IFQ species;

(G) Alaska State fish ticket number(s) for the landing;

(H) ADF&G statistical area of harvest reported by the IFQ cardholder;

(I) If ADF&G statistical area is bisected by a line dividing two IFQ regulatory areas, the IFQ regulatory area of harvest reported by the IFQ cardholder;

(J) For each ADF&G statistical area of harvest, the species codes, product codes, and initial accurate scale weight (in pounds or to the nearest thousandth of a metric ton) made at the time of offloading for IFQ species sold and retained. Exception: if the vessel operator is the Registered Buyer reporting the IFQ landing, the accurate weight of IFQ sablefish processed product obtained before the offload may be substituted for the initial accurate scale weight at time of offload.

(K) Whether ice and slime are present on the fish as offloaded from the vessel. Fish which have been washed prior to weighing or which have been offloaded from refrigerated salt water are not eligible for a 2-percent deduction for ice and slime and must indicate NO SLIME & ICE.

(L) If IFQ halibut is incidental catch concurrent with legal landing of salmon or concurrent with legal landing of lingcod harvested using dinglebar gear.

(M) After the Registered Buyer enters the landing data in the transaction terminal or the Internet submission form(s) and a receipt is printed, the Registered Buyer, or his/her representative, and the IFQ cardholder must sign the receipt(s) to acknowledge the accuracy of the Landing Report.

(iv) *Submittals*—(A) *Transaction terminal.* Except as indicated in paragraphs (l)(2)(iv)(B) and (C) of this

section, electronic Landing Reports must be submitted to OLE, Juneau, AK, using magnetic strip cards issued by NMFS, Alaska Region, and transaction terminals with printers driven by custom-designed software as provided and/or specified by NMFS, Alaska Region. The Registered Buyer must locate or procure a transaction terminal and report as required. The IFQ cardholder must initiate a Landing Report by using his or her own magnetic card and personal identification number (PIN).

(B) *Internet.* Electronic Landing Reports may be submitted to OLE, Juneau, AK, using Internet submission methods as provided and/or specified by NMFS, Alaska Region. It is the responsibility of the Registered Buyer to obtain at his or her own expense, hardware, software and Internet connectivity to support Internet submissions and report as required.

(C) *Manual landing report.* Waivers from the transaction terminal or Internet reporting requirement can only be granted in writing on a case-by-case basis by a local clearing officer. If a waiver is granted, manual landing instructions must be obtained from OLE, Juneau, AK, at 800–304–4846. Registered Buyers must complete and submit manual Landing Reports by FAX to OLE, Juneau, AK, at 907–586–7313. When a waiver is issued, the following additional information is required: Whether the manual Landing Report is an original or revised; and name, telephone number, and FAX number of individual submitting the manual Landing Report.

(D) *Properly debited landing.* A properly concluded transaction terminal receipt, printed Internet submission receipt, or manual Landing Report receipt received by FAX from OLE, Juneau, AK, and signed by an OLE representative constitutes confirmation that OLE received the Landing Report and that the cardholder's account was properly debited.

(3) *Transshipment authorization.* (i) No person may transship processed IFQ halibut or IFQ sablefish between vessels without authorization by a local clearing officer. Authorization from a local clearing officer must be obtained for each instance of transshipment at least 24 hours before the transshipment is intended to commence.

(ii) *Information required.* To obtain a Transshipment Authorization, the vessel operator must provide the following information to the clearing officer:

(A) Date and time (A.l.t.) of transshipment;

(B) Location of transshipment;

(C) Name and ADF&G vessel registration number of vessel offloading transshipment;

(D) Name of vessel receiving the transshipment;

(E) Product destination;

(F) Species and product type codes;

(G) Total product weight;

(H) Time (A.l.t.) and date of the request;

(I) Name, telephone number, FAX number (if any) for the person making the request.

(4) *IFQ Departure Report*—(i) *General Requirements*—(A) *Time limit and submittal.* A vessel operator who intends to make an IFQ halibut, CDQ halibut, or IFQ sablefish landing at any location other than in an IFQ regulatory area or in the State of Alaska must submit an IFQ Departure Report, by telephone, to OLE, Juneau, AK, at 800–304–4846 or 907–586–7163 between the hours of 0600 hours, A.l.t., and 2400 hours, A.l.t.

(B) *Completion of fishing.* A vessel operator must submit an IFQ Departure Report after completion of all fishing and prior to departing the waters of the EEZ adjacent to the jurisdictional waters of the State of Alaska, the territorial sea of the State of Alaska, or the internal waters of the State of Alaska when IFQ halibut, CDQ halibut, or IFQ sablefish are on board.

(C) *IFQ Registered Buyer permit.* A vessel operator submitting an IFQ Departure Report must have an IFQ Registered Buyer permit.

(D) *First landing of any species.* A vessel operator submitting an IFQ Departure Report must submit IFQ Landing Reports for all IFQ halibut, CDQ halibut, and IFQ sablefish on board at the same time and place as the first landing of any IFQ species.

(E) *IFQ permits on board.* A vessel operator submitting an IFQ Departure Report must ensure that one or more IFQ cardholders are on board with enough remaining IFQ balance to harvest amounts of IFQ halibut, CDQ halibut or IFQ sablefish equal to or greater than all IFQ halibut, CDQ halibut and IFQ sablefish on board.

(ii) *Required information.* When submitting an IFQ Departure Report, the vessel operator must provide the following information:

(A) Intended date, time (A.l.t.), and location of landing;

(B) Vessel name and ADF&G registration number;

(C) Vessel operator's name and IFQ Registered Buyer permit number;

(D) Halibut IFQ Permit numbers and sablefish IFQ Permit numbers of IFQ cardholders on board;

(E) Halibut Regulatory Areas or Sablefish Regulatory Areas of harvest or both;

(F) Estimated total weight of IFQ halibut or CDQ halibut on board (lb/kg/mt);

(G) Estimated total weight of IFQ sablefish on board (lb/kg/mt).

(5) *Landing verification, inspection and record retention*—(i) *Verification and inspection.* Each IFQ landing and all fish retained on board the vessel making an IFQ landing are subject to verification and inspection by authorized officers.

(ii) *Record retention.* The IFQ cardholder must retain a legible copy of all Landing Report receipts and the Registered Buyer must retain a copy of all reports and receipts required by this section and make them available for inspection by an authorized officer:

(A) Until the end of the fishing year during which the records were made and for as long thereafter as fish or fish products recorded are retained; and

(B) Upon request of an authorized officer for 3 years after the end of the fishing year during which the records were made.

(6) *Sampling*—(i) Each IFQ halibut landing and all fish retained on board a vessel making an IFQ landing are subject to sampling by NMFS-authorized observers.

(ii) Each IFQ halibut landing is subject to sampling for biological information by persons authorized by the IPHC.

* * * * *

5. In § 679.7, paragraphs (f)(6) and (f)(12) are revised to read as follows:

§ 679.7 Prohibitions.

* * * * *

(f) * * *

(6) *Landing*—(i) *IFQ or CDQ card.* Make an IFQ halibut, IFQ sablefish, or CDQ halibut landing without an IFQ or CDQ card in the name of the individual making the landing.

(ii) *Hired master.* Make an IFQ halibut, IFQ sablefish, or CDQ halibut landing without an IFQ or CDQ card listing the name of the hired master and the name of the vessel making the landing.

* * * * *

(12) Commence an IFQ landing without a Prior Notice of Landing (PNOL), before the date and time stated on the PNOL, or more than 2 hours after the date and time stated on the PNOL, except as provided in § 679.5(l)(1).

* * * * *

6. In § 679.32, paragraph (f)(2)(iv) is revised to read as follows:

§ 679.32 Groundfish and halibut CDQ catch monitoring.

* * * * *

(f) * * *

(2) * * *

(iv) *Landings.* A person may land halibut CDQ only if he or she has a valid CDQ card, and that person may deliver halibut CDQ only to a person with a valid Registered Buyer permit. The person holding the halibut CDQ card and the Registered Buyer must comply with the requirements of § 679.5(g) and (l).

* * * * *

7. In § 679.42, paragraphs (a), (c)(1)(ii), (c)(1)(iv), and (c)(2)(i) are revised to read as follows:

§ 679.42 Limitations on use of QS and IFQ.

(a) *IFQ regulatory area and vessel category.* (1) The QS or IFQ specified for one IFQ regulatory area must not be used in a different IFQ regulatory area.

(2) Except as provided in § 679.41(i)(1) of this part, the IFQ assigned to one vessel category must not be used to harvest IFQ species on a vessel of a different vessel category.

(3) Notwithstanding § 679.40(a)(5)(ii), IFQ assigned to vessel Category B must not be used on any vessel less than or equal to 60 ft (18.3 m) LOA to harvest IFQ halibut in IFQ regulatory area 2C or IFQ sablefish in the IFQ regulatory area east of 140° W. long. unless such IFQ derives from blocked QS units that result in IFQ of less than 5,000 lb (2.268 mt), based on the 1996 TAC for fixed gear specified for the IFQ halibut fishery and the IFQ sablefish fishery in each of these two regulatory areas.

* * * * *

(c) * * *

(1) * * *

(ii) Be aboard the vessel at all times during the fishing trip and present during the landing.

* * * * *

(iv) Sign the IFQ Landing Report required by § 679.5(l)(2)(iii)(M) or § 679.5(l)(2)(iv)(C).

(2) * * *

(i) Except as provided in § 679.5(l)(2)(iii)(J), if offload of unprocessed IFQ halibut, CDQ halibut or IFQ sablefish from a vessel, the scale weight of the halibut or sablefish product actually measured at the time of offload, as required by § 679.5(l)(2)(iii) to be included in the IFQ Landing Report.

* * * * *

8. In § 679.43, paragraph (c)is revised to read as follows:

§ 679.43 Determinations and appeals.

* * * * *

(c) *Submission of appeals.* Appeals must be in writing and must be mailed to the: National Marine Fisheries Service, Office of Administrative Appeals (OAA), P. O. Box 21668, Juneau, AK 99802–1668, or delivered to National Marine Fisheries Service, Attention: Appeals (OAA), 709 W. 9th Street, Room 453, Juneau, AK 99801.

* * * * *

9. In part 679, Tables 14a, 14b, and 14c are revised to read as follows:

TABLE 14A TO PART 679. PORT OF LANDING CODES, ALASKA [1]

Port name	NMFS code	ADF&G code
Adak	186	ADA
Akutan	101	AKU
Akutan Bay	102	
Alitak	103	ALI
Anchor Point	104	
Anchorage	105	ANC
Angoon	106	ANG
Aniak		ANI
Anvik		ANV
Atka	107	ATK
Auke Bay	108	
Baranof Warm Springs.	109	
Beaver Inlet	110	
Bethel		BET
Captains Bay	112	
Chefornak	189	
Chignik	113	CHG
Chinitna Bay	114	
Cordova	115	COR
Craig	116	CRG
Dillingham	117	DIL
Douglas	118	
Dutch Harbor/Unalaska.	119	DUT
Edna Bay	121	
Egegik	122	EGE
Ekuk		EKU
Elfin Cove	123	ELF
Emmonak		EMM
Excursion Inlet	124	XIP
False Pass	125	FSP
Fairbanks		FBK
Galena		GAL
Glacier Bay		GLB
Glennallen		GLN
Gustavus	127	GUS
Haines	128	HNS
Halibut Cove	130	
Hollis	131	
Homer	132	HOM
Hoonah	133	HNH
Hooper Bay	188	
Hydaburg		HYD
Hyder	134	HDR
Ikatan Bay	135	
Juneau	136	JNU
Kake	137	KAK
Kaltag		KAL
Kasilof	138	KAS
Kenai	139	KEN
Kenai River	140	
Ketchikan	141	KTN
King Cove	142	KCO
King Salmon	143	KNG

TABLE 14A TO PART 679. PORT OF LANDING CODES, ALASKA [1]—Continued

Port name	NMFS code	ADF&G code
Kipnuk	144	
Klawock	145	KLA
Kodiak	146	KOD
Kotzebue		KOT
La Conner		LAC
Mekoryuk	147	
Metlakatla	148	MET
Moser Bay		MOS
Naknek	149	NAK
Nenana		NEN
Nikiski (or Nikishka)	150	NIK
Ninilchik	151	NIN
Nome	152	NOM
Nunivak Island		NUN
Old Harbor	153	OLD
Other Alaska [1]	499	UNK
Pelican	155	PEL
Petersburg	156	PBG
Point Baker	157	
Port Alexander	158	PAL
Port Armstrong		PTA
Port Bailey	159	PTB
Port Graham	160	GRM
Port Lions		LIO
Port Moller		MOL
Port Protection	161	
Portage Bay (Petersburg).	162	
Quinhagak	187	
Resurrection Bay	163	
Sand Point	164	SPT
Savoonga	165	
Seldovia	166	SEL
Seward	167	SEW
Sitka	168	SIT
Skagway	169	SKG
Soldotna		SOL
St. George	170	STG
St. Lawrence	171	
St. Mary		STM
St. Paul	172	STP
Tee Harbor	173	
Tenakee Springs	174	TEN
Thorne Bay	175	
Togiak	176	TOG
Toksook Bay	177	
Tununak	178	
Ugadaga Bay	179	
Ugashik		UGA
Unalakleet		UNA
Valdez	181	VAL
Wasilla		WAS
West Anchor Cove	182	
Whittier	183	WHT
Wrangell	184	WRN
Yakutat	185	YAK

[1] To report a landing at a location not currently assigned a location code number: use the code for ''Other'' for the state or country at which the landing occurs and notify NMFS of the actual location so that the list may be updated. For example, to report a landing for Levelock, Alaska if there is currently no code assigned, use ''499'' ''Other, AK''.

TABLE 14B TO PART 679.—PORT OF LANDING CODES: CALIFORNIA, OREGON, CANADA

Port name	NMFS code	ADF&G code
California:		
Eureka	500	EUR
Fort Bragg	501	
Other California	599	
Oregon:		
Astoria	600	AST
Lincoln City	602	
Newport	603	NPT
Olympia	.....	OLY
Portland	.....	POR
Warrenton	604	
Other Oregon	699	
Canada:		
Port Edward	800	
Port Hardy	801	
Prince Rupert	802	PRU

TABLE 14B TO PART 679.—PORT OF LANDING CODES: CALIFORNIA, OREGON, CANADA—Continued

Port name	NMFS code	ADF&G code
Vancouver	803	
Other Canada	899	

TABLE 14C TO PART 679.—WASHINGTON PORT OF LANDING CODES

Port name	NMFS code	ADF&G code
Anacortes	700	ANA
Bellevue	701	
Bellingham	702	
Blaine	.....	BLA
Edmonds	703	
Everett	704	

TABLE 14C TO PART 679.—WASHINGTON PORT OF LANDING CODES—Continued

Port name	NMFS code	ADF&G code
Fox Island	706	
Ilwaco	707	
La Conner	708	LAC
Mercer Island	709	
Nagai Island	710	
Port Angeles	711	
Port Orchard	712	
Port Townsend	713	
Rainier	714	
Seattle	715	SEA
Tacoma	.....	TAC
Other Washington	799	

[FR Doc. 03–704 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 68, No. 16

Friday, January 24, 2003

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

Office of the Secretary

[Docket No. 03–001–2]

Declaration of Extraordinary Emergency Because of Exotic Newcastle Disease in Nevada

Exotic Newcastle disease (END) has been confirmed in the State of Nevada. The disease has been confirmed in backyard poultry, which are raised on private premises for hobby, exhibition, and personal consumption. Previously, END had been confirmed in the State of California, and on January 6, 2003, the Secretary of Agriculture signed a declaration of extraordinary emergency with respect to the END situation in California (*see* 68 FR 1432, Docket No. 03–001–1, published January 10, 2003).

END is a contagious and fatal viral disease affecting domestic, wild, and caged poultry and birds. It is one of the most infectious diseases of poultry in the world, and is so virulent that many birds die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. END can infect and cause death even in vaccinated poultry. This disease in poultry and birds is characterized by respiratory signs accompanied by nervous manifestations, gastrointestinal lesions, and swelling of the head.

END is spread primarily through direct contact between healthy birds or poultry and the bodily discharges of infected birds or poultry. Within an infected flock, END is transmitted by direct contact, contaminated feeding and watering equipment, and aerosols produced by coughing, gasping, and other respiratory disturbances. Dissemination between flocks over long distances is often due to movement of contaminated equipment and service personnel, such as vaccination crews. Movement of carrier birds and those in an incubating stage accounts for most of the outbreaks in the pet bird industry.

The existence of END in Nevada represents a threat to the U.S. poultry and bird industries. It constitutes a real danger to the national economy and a potential serious burden on interstate and foreign commerce. The United States Department of Agriculture (the Department) has reviewed the measures being taken by Nevada to control and eradicate END and has consulted with the appropriate State government and Indian tribal officials in Nevada. Based on such review and consultation, the Department has determined that the measures being taken by the State are inadequate to control or eradicate END. Therefore, the Department has determined that an extraordinary emergency exists because of END in Nevada.

This declaration of extraordinary emergency authorizes the Secretary to (1) hold, seize, treat, apply other remedial actions to, destroy (including preventative slaughter), or otherwise dispose of, any animal, article, facility, or means of conveyance if the Secretary determines the action is necessary to prevent the dissemination of END and (2) prohibit or restrict the movement or use within the State of Nevada, or any portion of the State of Nevada, of any animal or article, means of conveyance, or facility if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of END. The appropriate State government and Indian tribal officials in Nevada have been informed of these facts.

EFFECTIVE DATE: This declaration of extraordinary emergency shall become effective January 17, 2003.

Ann M. Veneman,

Secretary of Agriculture.

[FR Doc. 03–1610 Filed 1–23–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Yakutat Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Yakutat Resource Advisory Committee will meet in Yakutat, Alaska. The purpose of the meeting is to continue business of the Yakutat Resource Advisory Committee. The committee was formed to carry out the requirements of the Secure Rural Schools and Self-Determination Act of 2000. The agenda for this meeting is to finalize the form that the Yakutat Resource Advisory Committee will use to solicit project proposals and to determine what criteria they will use to select projects. The intent of the meeting is also to share with the public the project proposal process.

DATES: The meeting will be held February 7, 2003 from 6–9 p.m. and will continue on February 8, 2003 from 9–12 a.m., if necessary.

ADDRESSES: The meeting will be held at the Kwaan Conference Room, 712 Ocean Cape Drive, Yakutat, Alaska. Send written comments to Tricia O'Connor, c/o Forest Service, USDA, PO Box 327, Yakutat, AK 99689, (907) 784–3359 or electronically to *poconnor@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Tricia O'Connor, District Ranger and Designated Federal Official, Yakutat Ranger District, (907) 784–3359.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Council discussion is limited to Forest Service staff and Council members. However, persons who wish to bring resource projects or other Resource Advisory Committee matters to the attention of the Council may file written statements with the Council staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by January 31, 2003 will have the opportunity to address the Council at those sessions.

Dated: January 14, 2003.

Patricia M. O'Connor,

District Ranger, Yakutat Ranger District, Tongass National Forest.

[FR Doc. 03–1570 Filed 1–23–03; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to 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.

Comments Must Be Received On or Before: February 23, 2003.

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: Sheryl D. Kennerly, (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.

If the Committee approves the proposed additions, the entities of the Federal Government identified in the 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. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. If approved, 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 are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Electronic Service Customer Representative Service, Securities & Exchange Commission Library, Washington, DC.

NPA: Columbia Lighthouse for the Blind, Washington, DC.

Contract Activity: U.S. Securities and Exchange Commission, Alexandria, Virginia.

Service Type/Location: Housekeeping Services, Veterans Affairs Medical Center, Clarksburg, West Virginia.

NPA: Job Squad, Inc., Clarksburg, West Virginia.

Contract Activity: Department of Veterans Affairs, Coatesville, Pennsylvania.

Service Type/Location: Janitorial/Grounds Maintenance, Immigration and Naturalization Service—Sector Headquarters, Imperial, California.

NPA: Association for Retarded Citizens—Imperial Valley, El Centro, California

Contract Activity: Immigration and Naturalization Service, DOJ.

G. John Heyer,

General Counsel.

[FR Doc. 03–1662 Filed 1–23–03; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from Procurement List.

SUMMARY: This action adds to the Procurement List a product and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List a product and services previously furnished by such agencies.

EFFECTIVE DATE: February 23, 2003.

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: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION:

Additions

On September 13, November 29, and December 6, 2002, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (67 FR 58013, 71133, and 72640) of proposed additions to the Procurement List.

The following comments pertain to the Custodial Service, Walter Reed Army Medical Center.

Comments were received from a small disadvantaged business firm which holds a contract for other custodial services at Walter Reed Army Medical Center under the 8(a) Program. The commenter noted that it had been pursuing the custodial service being added to the Procurement List for several years, and that a number of its other contracts are expiring and not being replaced by new work. Consequently, the commenter believes that loss of the opportunity to win the contract for the custodial service being added to the Procurement List will constitute a severe adverse impact on the firm.

The Committee does not consider the loss of an opportunity to bid for contracts on this service, by itself, to constitute severe adverse impact on a firm, as no firm is guaranteed a contract under the competitive bidding system. The commenting firm has not held a contract for the custodial service being added to the Procurement List, so it cannot be said to be dependent on such a contract. The Committee originally contemplated adding the entire custodial service at Walter Reed Army Medical Center to the Procurement List, but declined to do so in order to minimize impact on the commenting firm. The commenter will retain its current contract at Walter Reed Army Medical Center and will remain eligible to pursue contracting opportunities in the 8(a) Program, as well as other competitive opportunities, for the near future. At the commenter's request, the Committee has facilitated discussions between the commenter and the nonprofit agency which will provide the service being added to the Procurement List, with a view toward further mitigating impact on the contractor through possible subcontracting opportunities. Accordingly, the Committee does not believe that addition of this portion of the custodial service at Walter Reed Army Medical Center to the Procurement List at this time will constitute severe adverse impact on the commenting firm.

The following material pertains to all of the items being added to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product and services and impact of the additions on the current or most recent contractors, the Committee has determined that the product and services listed below are 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 product and services to the Government.

2. The action will result in authorizing small entities to furnish the product and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the product and services proposed for addition to the Procurement List.

Accordingly, the following product and services are added to the Procurement List:

Product

Product/NSN: Marker, Dry Erase, Premium, 7520–00–NIB–1428
NPA: Dallas Lighthouse for the Blind, Inc., Dallas, Texas
Contract Activity: Office Supplies & Paper Product Acquisition Center, New York, New York

Services

Service Type/Location: Custodial Service, Walter Reed Army Medical Center, Main Section, Washington, DC, Forest Glen Section, Montgomery County, MD: Buildings 1, 5, 11, 52, 53, 92, 121, 154, 156, 163, 169, 178, 500, 501, 508, 511, 512, 601, 602, 604, and 605
NPA: Mt. Vernon-Lee Enterprises, Inc., Springfield, Virginia
Contract Activity: MEDCOM Contracting Center-NA, Washington, DC
Service Type/Location: Medical Transcription, Department of Veterans Affairs, VAMC Boise, Idaho
NPA: The Lighthouse of Houston, Houston, Texas
Contract Activity: Veterans Affairs Medical Center, Boise, Idaho

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 may not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the product and service deleted from the Procurement List.

After consideration of the relevant matter presented, the committee has determined that the product and service 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 product and service are deleted from the Procurement List:

Product

Product/NSN: Aerosol Paint, Lacquer, 8010–00–958–8147
NPA: The Lighthouse for the Blind, Inc., St Louis, Missouri
Contract Activity: GSA, Hardware & Appliances Center, Kansas City, Missouri

Service

Service Type/Location: Base Supply Center, New Orleans Naval Support Activity, New Orleans, Louisiana
NPA: Raleigh Lions Clinic for the Blind, Inc., Raleigh, North Carolina
Contract Activity: Department of the Navy, New Orleans, Louisiana

G. John Heyer,

General Counsel.

[FR Doc. 03–1663 Filed 1–23–03; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Institute of Standards and Technology (NIST).

Title: Survey of Advanced Technology Program Joint Venture Participants.

Form Number: None.

OMB Approval Number: None.

Type of Request: Regular.

Number of Respondents: 547.

Average Hours Per Response: 30 minutes for the Company survey; 15 minutes for the Nonprofit Organization survey; and 10 minutes for the Inactive Company survey.

Needs and Uses: This information collection is for program evaluation of the Advanced Technology Program (ATP). Research and development (R&D) collaborations and strategic alliances across companies and organizations have become increasingly important in industry. A key mission of the ATP as defined by statute is to support R&D joint ventures. This information collection and analysis will further ATP's mission by providing better understanding of R&D collaborations in general, and ATP Joint Ventures in particular.

Affected Public: Business or other for-profit organizations, not-for-profit institutions.

Frequency: One-time only.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Jacqueline Zeiher, (202) 395–4638.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *DHynek@doc.gov)*.

Written comments and recommendations for this proposed information collection should be sent within 30 days of publication of this notice to Jacqueline Zeiher, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: January 17, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1586 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-823–808]

Certain Cut-to-Length Carbon Steel Plate from Ukraine; Administrative Review of Suspension Agreement; Extension of Time Limits

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

ACTION: Notice of Extension of Time Limits.

SUMMARY: The Department of Commerce (the Department) is extending the time limits for the final results of the 2000–2001 administrative review of the suspension agreement on cut-to-length carbon steel plate from Ukraine.

EFFECTIVE DATE: January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Patricia Tran at (202) 482–1121 or Robert James at (202) 482–0649, Antidumping and Countervailing Duty Enforcement Group III, Office Eight, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On December 9, 2002, we published the preliminary results of this administrative review. *See Certain Cut-*

to-Length Carbon Steel Plate from Ukraine; Notice of Preliminary Results of Administrative Review of the Suspension Agreement 67 FR 72916 (December 9, 2002). Currently, the final results in this administrative review are due on April 8, 2003. Pursuant to section 751(a)(3)(A) of the Tariff Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the final results of the review within the normal statutory time limit. Due to the complexity of the issues present in this administrative review, including affiliated party sales, and because the Department must conduct verifications of several discreet entities, the Department determines it is not practicable to complete this review within the normal statutory time limit. Therefore, the Department is extending the time limits for completion of the final results until June 9, 2003, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended.

Dated: January 15, 2003.

Joseph A. Spetrini,

Deputy Assistant Secretary for Import Administration, Group III.

[FR Doc. 03–1654 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570–855]

Certain Non-Frozen Apple Juice Concentrate From the People's Republic of China: Extension of Time Limit for the Preliminary Results of the 2001–2002 Antidumping Duty Administrative Review and New Shipper Review

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

ACTION: Extension of Time Limit.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary results of the 2001–2002 administrative review of the antidumping duty order and new shipper review on certain non-frozen apple juice concentrate from the People's Republic of China. The period of review is June 1, 2001, through May 31, 2002. This extension is made pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended.

EFFECTIVE DATE: January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Audrey Twyman, or John Brinkmann, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–3534, or (202) 482–4126, respectively.

SUPPLEMENTARY INFORMATION:

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930 (''the Act'') requires the Department of Commerce (''Department'') to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested and a final determination within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend these deadlines to a maximum of 365 days and 180 days, respectively. The order in this review was published on June 5, 2000. (*See Notice of Amended Determination of Sales at Less than Fair Value and Antidumping Duty Order: Certain Non-frozen Apple Juice Concentrate from the PRC*, 65 FR 35606 (June 5, 2000)).

Background

On July 24, 2002, the Department published in the **Federal Register** the notice of initiation of the antidumping administrative review on certain non-frozen apple juice concentrate from the People's Republic of China (PRC). (*See Notice of Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 67 FR 48435 (July 24, 2002)). The preliminary results are currently due on March 2, 2003. On July 24, 2002, the Department also published in the **Federal Register** the notice of initiation of antidumping new shipper review on certain non-frozen apple juice concentrate from the People's Republic of China (PRC). (**SEE NOTICE OF INITIATION OF ANTIDUMPING NEW SHIPPER REVIEW**, 67 FR 48440 (July 24, 2002)). On July 26, 2002, Gansu Tongda Fruit Juice and Beverage Co., Ltd., the respondent in the new shipper review, submitted a letter consenting to alignment of the new shipper review with the 2001–2002 administrative review pursuant to 19 CFR 351.214(j)(3).

Extension of Time Limits for Preliminary Results

Due to the complexity of the issues involving surrogate selection and factor values, it is not practicable to complete this review within the originally anticipated time limit (*i.e.*, March 2, 2003). Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is postponing the preliminary results of this administrative review for 120 days, until no later than June 30, 2003.

This notice is published pursuant to sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 17, 2003.

Susan Kuhbach,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 03–1653 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012103A]

Proposed Information Collection; Comment Request; Northwest Region Federal Fisheries Permits

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Kevin A. Ford, NOAA Fisheries, Northwest Region, 206–526–6115 or e-mail at *kevin.ford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Two data collections dealing with Federal fishery permits affect participants in the groundfish fishery off Washington, Oregon, and California (WOC). The two data collections involve: (1) exempted fishing; and (2) limited entry permits for commercial fishermen.

Exempted (experimental) fishing permits are issued to applicants for fishing activities that would otherwise be prohibited. The information provided by applications allows the National Marine Fisheries Service (NMFS) to evaluate the consequences of the exempted fishing activity and weigh the benefits and costs. Permittees are required to file reports on the results of the experiments and in some cases individual vessels are required to provide minimal data reports. There is also a requirement for a call-in notification prior to a fishing trip. This information allows NOAA Fisheries to evaluate techniques used and decide if management regulations should be changed.

A Federal permit is required to commercially catch groundfish, and permits are endorsed for one or more of three gear types (trawl, longline, and fish pot). Participation in the fishery and access to permits have been limited as a way of controlling the overall fleet harvest capacity. Limited entry permits must be renewed annually and are transferable. Permit owners must fill out renewal forms annually and must fill out transfer forms, as needed.

II. Method of Collection

Permit applications, renewals, and transfers are made on NOAA Fisheries forms. Renewal of limited entry permits also may be completed electronically using an online form on the Fishery Permit Office Web site. The exempted fishing data reports from individual vessels may be submitted in person, faxed, or submitted by telephone by the vessel owner or operator to NOAA Fisheries or the states of Washington, Oregon, or California.

III. Data

OMB Number: 0648–0203.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 707.
Estimated Time Per Response: 20 minutes for a limited entry permit renewal or transfer; 60 minutes for an experimental fishery permit application; 60 minutes for an experimental fishery permit summary report; 10 minutes for an experimental fishery data report; and 2 minutes for an experimental fishery call-in notification prior to a fishing trip.
Estimated Total Annual Burden Hours: 341.
Estimated Total Annual Cost to Public: $46,616.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 16, 2003

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1646 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012103B]

Proposed Information Collection; Comment Request; Groundfish Tagging Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Phillip Rigby at 907–789–6653, or at *Phillip.Rigby@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The groundfish tagging program provides scientists with information necessary for effective conservation, management, and scientific understanding of the groundfish fishery off Alaska and the Northwest Pacific. The program area includes the Pacific Ocean off Alaska (the Gulf of Alaska, the Bering Sea and Aleutian Islands Area, and the Alexander Archipelago of Southeast Alaska), California, Oregon, and Washington. Fish movement information from recovered tags is used in population dynamics models for stock assessment.

II. Method of Collection

This is a volunteer program requiring the actual tag from the fish to be returned, along with recovery information. Reporting forms with pre-addressed and postage-free envelopes are distributed to processors and catcher vessels. The tag information will be edited and entered into the computer data base. Each person returning a tag will receive information on the release site, growth, and depth and area changes, as well as a reward of a cap.

III. Data

OMB Number: 0648–0276.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations, individuals or households.
Estimated Number of Respondents: 820.
Estimated Time Per Response: 5 minutes for returning a regular tag; and 20 minutes for returning an internal archival tag.
Estimated Total Annual Burden Hours: 73.
Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 16, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1647 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012103C]

Proposed Information Collection; Comment Request; Northeast Region Multispecies Party/Charterboat Closed Area Exemption Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Thomas Warren at 978–281–9250, or to *Thomas.Warren@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Northeast multispecies party and charter vessels must obtain a letter of authorization from NOAA in order to fish for multispecies in certain areas of the Gulf of Maine closed to commercial fishing (Nantucket Lightship Area Closure, Rolling Closures, Cashes Ledge Area Closure, and Western Gulf of Maine Area Closure). Because party or charter vessels may hold commercial fishing permits, the authorization program allows NOAA to enforce closed area requirements and ensure that fish harvested under recreational rules are not sold by party and charter vessels.

II. Method of Collection

Requests are made by telephone or in person.

III. Data

OMB Number: 0648–0412.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 528.

Estimated Time Per Response: 2 minutes.

Estimated Total Annual Burden Hours: 18.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 16, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1648 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012103D]

Proposed Information Collection; Comment Request; Paperwork Submissions Under the Coastal Zone Management Act Federal Consistency Requirements

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to David Kaiser, 301–713–3098, ext. 144 or at *David.Kaiser@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

A number of paperwork submissions are required by the Coastal Zone Management Act (CZMA), 16 U.S.C. 1456, and by NOAA to provide a reasonable, efficient and predictable means of complying with the CZMA requirements. The requirements are detailed in 15 CFR Part 930. The information will be used by coastal States with Federally-approved Coastal Zone Management Programs to determine if Federal agency activities, Federal license or permit activities, and Federal assistance activities that affect a State's coastal zone are consistent with the States' programs.

II. Method of Collection

Paper submissions are made following regulatory guidance. No forms are used.

III. Data

OMB Number: 0648–0411.

Form Number: None.

Type of Review: Regular submission.

Affected Public: State, Local, or Tribal Government; individuals or households; business or other for-profit organizations; and Federal government.

Estimated Number of Respondents: 4,111.

Estimated Time Per Response: 8 hours for a State objection or concurrence letter for a consistency certification or determination; 4 hours for a State request for review of unlisted activities; 1 hour for public notice requirements for a project; 4 hours for a request for remedial action of a supplemental review; 1 hour for coordination of a listing notice; 2 hours for a request for Secretarial mediation; and 200 hours for an appeal. These are average estimates and burden can significantly vary based on the individual situation.

Estimated Total Annual Burden Hours: 20,331.

Estimated Total Annual Cost to Public: $8,000,000.

IV. Request for Comments

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 16, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1649 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–08–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Federal Consistency Appeal by Islander East Pipeline Company From an Objection by the Connecticut Department of Environmental Protection

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (Commerce).

ACTION: Notice of appeal, request for comment, and notice of availability of appeal documents.

SUMMARY: The Islander East Pipeline Company has filed an administrative appeal with the Department of Commerce (Consistency Appeal of Islander East Pipeline Company, L.L.C.) asking that the Secretary of Commerce override the State of Connecticut's objection to Islander East's proposed natural gas pipeline. The pipeline would extend from an interconnection with an existing pipeline near North Haven, Connecticut, to a terminus on Long Island, New York, affecting the natural resources or land and water uses of Connecticut's coastal zone. This document: (a) Provides public notice of the appeal; (b) announces an opportunity for public comment on the appeal; and (c) identifies locations where documents comprising the appeal record will be available for review.

DATES: Public comments on the appeal must be received by May 8, 2003.

ADDRESSES: All e-mail comments on issues relevant to the Secretary's decision of this appeal may be submitted to *IslanderEast.comments@noaa.gov.* Comments may also be sent by mail to the Office of the General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1305 East-West Highway, Silver Spring, MD 20910. Materials from the appeal record will be available at the internet site *www.ogc.doc.gov/czma.htm* and at the Office of the General Counsel for Ocean Services. Also, public filings made by the parties to the appeal will be available for review at the Connecticut Department of Environmental Protection, 79 Elm Street, Hartford, CT.

FOR FURTHER INFORMATION CONTACT: Branden Blum, Senior Counselor, via e-mail at *gcos.inquiries@noaa.gov,* or at 301–713–2967, extension 186.

SUPPLEMENTARY INFORMATION:

I. Notice of Appeal

Islander East Pipeline Company, L.L.C. (Islander East or Appellant) filed a notice of appeal with the Secretary of Commerce (Secretary) pursuant to section 307(c)(3)(A) of the Coastal Zone Management Act of 1972 (CZMA), as amended, 16 U.S.C. 1451 *et seq.,* and the Department of Commerce's implementing regulations, 15 CFR part 930, subpart H, (revised, effective January 8, 2001). The appeal is taken from an objection by the Connecticut Department of Environmental Protection (State) to Islander East's consistency certification for U.S. Army Corps of Engineers and Federal Energy Regulatory Commission permits to construct and operate a natural gas pipeline. The certification is required to indicate that the project is consistent with the State's coastal management program. The project would cross portions of the Long Island Sound, affecting the natural resources or land and water uses of Connecticut's coastal zone.

The Appellant request that the Secretary override the State's consistency objections on the two substantive grounds provided in the CZMA. The first ground requires the Secretary to determine that the proposed activity is ''consistent with the objectives'' of the CZMA. To make this determination, the Secretary must find that: (1) The proposed activity furthers the national interest as articulated in section 302 or 303 of the CZMA, in a significant or substantial manner; (2) the national interest furthered by the proposed activity outweighs the activity's adverse coastal effects, when those effects are considered separately or cumulatively; and (3) no reasonable alternative is available that would permit the proposed activity to be conducted in a manner consistent with the enforceable policies of the State of Connecticut's coastal zone management program. 15 CFR 930.121.

The second substantive ground for overriding a State's objection considers whether the proposed activity is necessary in the interest of national security. To reach this conclusion, the Secretary must find that a national defense or other national security interest would be significantly impaired if the activity in question was not permitted to go forward as proposed. 15 CFR 930.122.

II. Public Comments

Written public comments are invited on any of the issues that the Secretary must consider in deciding this appeal. Comments must be received by May 8,

2003, and may be submitted by e-mail to *IslanderEast.comments@noaa.gov.* Comments may also be sent by mail to the Office of the General Counsel for Ocean Services, National Oceanic and Atmospheric Administration (NOAA). Comments will be made available to the Appellant and the State; they will also be posted on a Department of Commerce website identified below.

III. Appeal Documents

The Secretary has required that Islander East file its initial brief and supplementary information on February 10, 2003, and that the State of Connecticut file its initial brief and supplementary material on March 24, 2003. NOAA intends to provide the public with access to all materials and related documents comprising the appeal record via the internet at *www.ogc.doc.gov/czma.htm,* except that certain materials or documents or portions thereof may be withheld if they contain confidential materials, critical energy infrastructure information, national security information or other types of information that would be inappropriate for public release. In addition, technical constraints may limit the internet availability of certain documents, such as oversized maps or exceedingly lengthy publications. All public materials and documents will be available during business hours at the NOAA Office of the General Counsel for Ocean Service. In addition, the State of Connecticut will make copies of public filings by the parties available for review during business hours at the office of the Connecticut Department of Environmental Protection.

(Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance)

Dated: January 21, 2003.

James R. Walpole,

General Counsel.

[FR Doc. 03–1634 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 020814191–2191–01]

Establishment of a Joint or Cooperative Institute Within the National Oceanic and Atmospheric Administration (NOAA) Office of Oceanic and Atmospheric Research (OAR) Joint and Cooperative Institute Program

AGENCY: Office of Oceanic and Atmospheric Research; National Oceanic and Atmospheric Administration; Department of Commerce.

ACTION: Notice of Request for Letters of Intent and Guidelines for Submission of Full Proposals.

SUMMARY: NOAA invites interested institutions to submit Letters of Intent (LOI) indicating interest in establishing a Joint or Cooperative Institute within the National Oceanic and Atmospheric Administration (NOAA) Office of Oceanic and Atmospheric Research (OAR) Joint and Cooperative Institute Program. The proposed name of the Joint Institute will be the Cooperative Institute for Climate Applications and Research. The OAR Joint and Cooperative Institute Program is listed in the CFDA under number 11.432, Office of Oceanic and Atmospheric Research (OAR) Joint and Cooperative Institutes.

The Institutes represent a close link between OAR laboratories, other branches of NOAA and the external research community. NOAA collaborates on cooperative research activities and provides financial support to enhance the public benefits to be derived from these research activities. The Institutes are established based on their geographical proximity to a NOAA facility, and/or their expertise in areas related to the mission of the NOAA/OAR research laboratories.

DATES: Letters of Intent should be submitted no later than February 24, 2003. Response letters will be issued from NOAA approximately 45 days after the date of the **Federal Register** Announcement. Institutions will be informed of the submittal date for full proposals in the response letter.

ADDRESSES: Letters of Intent and proposals should be submitted to: Dr. Ants Leetmaa; NOAA Geophysical Fluid Dynamics Laboratory; Forrestral Campus Rt. 1; P.O. Box 308; Princeton, NJ 08452–0308.

An Application Kit can be obtained from: Mr. Michael Nelson; NOAA Grants Management Division; Silver Spring Metro Center Bldg. 2, Room 9348; Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Dr. Ants Leetmaa; NOAA Geophysical Fluid Dynamics Laboratory; Forrestral Campus Rt. 1; P.O. Box 308; Princeton, NJ 08452–0308.

SUPPLEMENTARY INFORMATION:

I. Program Authority

Authority: 49 U.S.C. 44720; 33 U.S.C. 883d; 15 U.S.C. 2907; 15 U.S.C. 2931.

II. Program Description

Funding: The base funding for the Institute is expected to be $100,000 per year. However, funding is contingent upon availability of funds and is at the sole discretion of NOAA.

The funding instrument will be a Cooperative Agreement based on the envisioned substantial involvement of NOAA scientists in projects undertaken by the Institute. NOAA collaborates on cooperative research activities and provides financial support to enhance the public benefits to be derived from these research activities. NOAA envisions a sharing of expertise between GFDL and the proposed Institute in the areas of: earth system modeling, modern and paleoclimatic observations, and climate variability and change applications research. Funding for non-U.S. institutions and contractual arrangements for services and products for delivery to NOAA are not available under this announcement. The award will have an initial base term of five years. An OAR-sponsored, independent panel will conduct a review of the Institute during the fourth year of the five year term. The Panel's findings and recommendations will serve as the basis for renewal of the Institute for an additional five years.

Program Priorities: The Institute will be affiliated with the Geophysical Fluid Dynamics Laboratory (GFDL) located in Princeton, New Jersey. The Institute will align itself with the following GFDL research priorities:

a. *Earth System modeling:* Including, but not limited to, the development of dynamical models of the global climate system, and the production of forecasts of the long-term variability of the climate.

b. *Modern and paleoclimatic observations:* including but not limited to standard hydrographic observations and the construction and analysis of new proxies (*e.g.* geochemical and isotopic tracers in deep-sea sediments, aquifers, tree rings and ice cores) for studies of climate variability and change, including abrupt climate changes.

c. *Climate variability and change applications research:* including but not limited to the study of communication between forecasters and users of forecasts; the application of climate variability and change information to decision making in fields such as water resources, agriculture, human health, and policy making; and institutional mechanisms for responding to climate variability and change information.

The Institute is meant to be an integral component in a coordinated

research effort to produce the best possible forecasts of climate variability and change and to aid in the development of forecast guidance products that are socially and economically useful to decision makers. The Institute will promote research efforts designed to (1) develop coupled models of the global atmosphere, ocean, and land surface to serve as a basis for improved climate variability and change simulations and forecasts, (2) produce and analyze modern and paleoclimatic data that will be required for the verification of the simulations and forecasts, and (3) explore and develop methods that will facilitate the effective dissemination of the forecasts to decision makers.

III. Eligibility

Extramural eligibility is limited to U.S. institutions. Universities, non-profit organizations, for-profit organizations, State and local governments, and Indian Tribes, are included among entities eligible for funding under this announcement.

IV. Evaluation Criteria

Consideration for financial assistance will be given to those proposals that address the Program Priorities listed above and meets the following evaluation criteria. Equal weight is assigned to each of the criteria.

a. *Scientific Merit:* Intrinsic scientific value of the proposed research.

b. *Program Relevance:* Applicability to the OAR Joint and Cooperative Institute Program as described in Section II, Program Description.

V. Submission Requirements

The guidelines for proposal preparation provided below are mandatory. Failure to heed these guidelines will result in proposals being returned without review.

a. *Letters of Intent:* (1) Letters of Intent (LOI) are required prior to submission of a full proposal. (2) The LOI should be no more than ten pages in length and should include the name and institution of the principal investigator. (3) The LOI should provide a concise description of the proposed work. (4) The LOI should also provide a detailed description of the resources and capabilities of the host institution, specifically scientific expertise, specialized facilities, ongoing research activities, and educational and training programs. (5) Evaluation will be by OAR program management, according to the evaluation criteria for full proposals described above. (6) Institutions with an LOI deemed unresponsive will not be encouraged to submit full proposals, however they will not be precluded from submitting a full proposal.

b. *Full Proposals:* All proposals should include the following elements:

(1) *Signed title page:* The title page should be signed by the Principal Investigator (PI) and the institutional representative. The PI and institutional representative should be identified by full name, title, organization, telephone number, and address.

(2) *Abstract:* A one page abstract must be included and should contain a brief summary of the work to be completed. The abstract should appear on a separate page, headed with the proposal title, institution(s) investigators(s) , total proposed cost and budget period.

(3) *Statements of work:* All proposals should provide detailed five-year plans for climate variability and change modeling and prediction research, modern and paleoclimatic observations, and climate forecast applications which build upon the program outlined in the LOI. The following areas must be addressed in the proposal: Proposed mechanisms for the development and implementation of climate model improvements; creation and maintenance of a modern and paleoclimatic data base; strategy for generating experimental forecasts guidance products and their effective dissemination to decision makers. The proposed work should be described, including identification of the problems, scientific objectives, proposed methodology, and relevance to the program priorities listed above. Factors, such as readiness of needed infrastructure, ease of interaction with scientists at GFDL, amount and type of NOAA support presently received, benefits of the proposed work to the general public, the scientific community, and decision makers, should be described. Results from related projects previously and presently supported by NOAA should be included.

(4) *Budget:* Applicants must submit a budget using the Standard Form 424a(4–92), Budget Information—Non-Construction Programs. The form is included in the standard NOAA application kit.

(5) *Vita:* An abbreviated Curriculum Vita for the PI should be included. Reference lists should be limited to all publications in the last three years with up to five other relevant papers.

(6) *Current and pending Federal support:* Each investigator should submit a list that includes project title, supporting agency with grant number, investigator months, dollar value and duration. Requested values should be listed for pending federal support.

VI. Selection Procedures

All proposals will be evaluated in accordance with the above evaluation criteria by an independent peer review panel consisting of both NOAA and non-NOAA Federal experts. The panel will review and discuss each proposal and, based on the above evaluation criteria, make a consensus recommendation of the most meritorious and relevant proposal to the Selecting Official.

The Selecting Official may either accept the recommendation or select another proposal based on the following program policy factor: geographic diversity within the existing Joint Institute program. The selected proposal will be forwarded to the Grants Officer for action and the successful applicant notified.

VII. Other Requirements

(1) Applications under this program are not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.''

(2) In accordance with Federal statutes and regulations, no person on grounds of race, color, age, sex, national origin, or disability shall be excluded from participation in, denied benefits of, or be subjected to discrimination under any program or activity receiving financial assistance. The NOAA Office of Oceanic and Atmospheric Research does not have direct Telephone Device for the Deaf (TDD) capabilities, but can be reached through the State of Maryland-supplied TDD contact number, 800–735–2258, between the hours of 8 a.m.–4:30 p.m.

(3) The Department of Commerce Pre-Award Notification of Requirements for Grants and Cooperative Agreements contained in the **Federal Register** Notice of October 1, 2001, (66 FR 49917), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109), is applicable to this solicitation.

VIII. Classification

This notice has been determined to be not significant for purposes of Executive Order 12866. This notice contains collection-of-information requirements subject to the Paperwork Reduction Act. The use of Standard Forms 424, 424A, and SF–LLL has been approved by OMB under the respective control numbers 0348–0043, 0348–0044, and 0348–0046. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the Paperwork Reduction Act, unless that collection displays a currently valid OMB control number.

It has been determined that this notice does not contain policies with Federalism implications as that term is defined in Executive Order 13132. Because notice and comment are not required under 5 U.S.C. 553, or any other law, for this notice relating to public property, loans, grants benefits or contracts (5 U.S.C. 553(a)), a Regulatory Flexibility Analysis is not required and has not been prepared for this notice, 5 U.S.C. 601 *et seq.*

Dated: January 15, 2003.

Louisa Koch,

Deputy Assistant Administrator, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 03–1643 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–KB–P

DEPARTMENT OF COMMERCE

Technology Administration

Proposed Information Collection; Comment Request; Commercial Space Launch Range User Requirements

ACTION: Notice.

SUMMARY: The Department of Commerce (DOC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the continuing and proposed information collection, as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Paula Trimble, Technology Policy Analyst, Office of Space Commercialization, (202) 482–4574. In addition, written comments may be sent via e-mail to *SpaceInfo@ta.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The information collected would allow the DOC Office of Space Commercialization (DOC/OSC) and the Federal Aviation Administration (FAA) to follow the terms of a Memorandum of Agreement (MOA) with the U.S. Air Force to ensure consideration of commercial space launch range users' needs in the Air Force's range modernization planning. Air Force endorsement of this arrangement, and industry support for the process expressed through FAA's FACA-compliant Commercial Space Transportation Advisory Committee (COMSTAC), are highly significant, because this is the first time these parties have all agreed to a single formal communication channel for commercial range requirements. Based on experience with response to a preliminary October 2001 **Federal Register** (FR) information request, respondents to subsequent biannual FR solicitations are expected to be less than ten in number and to include the three companies that currently launch vehicles from the two major federal ranges, one or more new companies that may be planning to initiate launch services there, and one or more non-profit or state government entities electing to comment on range needs.

II. Method of Collection

Responses would normally be submitted as hard copy to the DOC/OSC and FAA docket addresses specified in the **Federal Register** announcement. Only for responses sent to FAA would the option be available to submit comments electronically, via the Internet to the FAA website address specified in the announcement.

III. Data

OMB Number: 0692–0009.

Form Numbers: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations; not-for-profit institutions; state, local, or tribal government.

Estimated Number of Respondents: 7.

Estimated Time Per Response: 10 hours.

Estimated Total Annual Respondent Burden Hours: 70.

Estimated Total Annual Respondent Cost Burden: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, *e.g.*, the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 17, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–1587 Filed 1–23–03; 8:45 am]

BILLING CODE 3510–18–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Defense Science Board (DSB) Task Force on the Role and Status of DoD Red Teaming Activities will meet in closed session on February 26, 2003; and March 24, 2003; at Strategic Analysis Inc., 3601 Wilson Boulevard, Arlington, VA. This Task Force will review the role and status of Red Teaming in the Department of Defense (DoD) and recommend ways to make it a more effective tool.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At these meetings, the Defense Science Board Task Force will review and evaluate current and past Red Team activities within the Department of Defense and its agencies, as well as other government and non-government organizations (including those initiated since September 11). The Task Force will prepare recommendations that are relevant to red teaming that portrays both state and non-state adversaries. It will also look at how the Department should work with other government departments and agencies to foster effective red teaming. The Task Force will address issues of red team products, processes and organization.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. II), it has been determined that these Defense Science Board Task Force meetings concern matters listed in 5 U.S.C. 552b(c)(1) and that, accordingly, these meetings will be closed to the public.

Dated: January 17, 2003.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03–1595 Filed 1–23–03; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF EDUCATION

Tech-Prep Demonstration Program

AGENCY: Office of Vocational and Adult Education, Department of Education.

ACTION: Notice of proposed requirements, proposed priorities and proposed selection criteria for Fiscal Year (FY) 2003 and subsequent years.

SUMMARY: The Assistant Secretary for the Office of Vocational and Adult Education proposes requirements, priorities and selection criteria under the Tech-Prep Demonstration Program (TPDP). The Assistant Secretary will use these requirements, priorities and selection criteria for a competition in fiscal year (FY) 2003 and may use them in later years. We intend these requirements, priorities and selection criteria to support the four basic education reform principles underlying the No Child Left Behind Act of 2001 (NCLB): Stronger accountability for results, increased flexibility and local control, expanded options for parents, and an emphasis on teaching methods that have been proven to work. We take this action to clarify the Department's expectations regarding this program, so that TPDP-funded projects will help students, schools and teachers in their efforts to improve student achievement, meet high standards for high school graduation, and increase transition and persistence rates in postsecondary education.

DATES: We must receive your comments on or before February 24, 2003.

ADDRESSES: Address all comments about these proposed priorities to Karen Stratman Clark, U.S. Department of Education, OVAE, MES Room 5223, 400 Maryland Avenue SW., Washington DC 20202–7100. If you prefer to send your comments through the Internet, use the following address: *Karen.clark@ed.gov*. You must include the term ''TPDP Proposed Requirements'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Karen Clark. Telephone: (202) 205–3779. or via Internet: *karen.clark@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339. Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Invitation to Comment

We invite you to submit comments regarding these proposed requirements, priorities and selection criteria. To ensure that your comments have maximum effect in developing the notice of final priorities, we urge you to identify clearly the specific proposed requirement, priority or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities. Please let me know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about these proposed priorities in Room 4328, 330 C Street, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed priorities. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: We propose to establish program requirements, priorities, selection criteria and a project period for the TPDP, which is authorized by section 207 of the Carl D. Perkins Vocational and Technical Education Act of 1998 (Perkins III). TPDP provides grants to consortia to carry out tech-prep education projects that involve the location of a secondary school on the site of a community college, a business as a member of the consortium, and the voluntary participation of secondary school students. We proposed to fund projects that, following an initial recruitment period, would enroll a new student cohort in each year of the project, in addition to continuing support for each previous TPDP student cohort.

Eligibility

To be eligible for funding under the TPDP, a consortium must include at least one member in each of the following three categories:

(1) A local educational agency, an intermediate educational agency, an area vocational and technical education school serving secondary school students, or a secondary school funded by the Bureau of Indian Affairs;

(2)(a) A nonprofit institution of higher education that offers a 2-year associate degree, 2-year certificate, or 2-year postsecondary apprenticeship program, or (b) a proprietary institution of higher education that offers a 2-year associate degree program; and

(3) A business.

Under the provisions of section 204(a)(1) of Perkins III, to be eligible for consortium membership both nonprofit and proprietary institutions of higher education must be qualified as institutions of higher education pursuant to section 102 of the Higher Education Act of 1965 (HEA), including institutions receiving assistance under the Tribally Controlled College or University Assistance Act of 1978 (25 U.S.C. 1801 *et seq.*) and tribally controlled postsecondary vocational and technical institutions.

In addition, nonprofit institutions of higher education are eligible only if they are not prohibited from receiving assistance under HEA, title IV, part B (20 U.S.C. 1071 *et seq.*), pursuant to the provisions of HEA section 435(a)(3) (20 U.S.C. 1083(a)). Proprietary institutions of higher education are eligible only if they are not subject to a default management plan required by the Secretary.

Under the provisions of section 204(a)(2), consortia also may include one or more: (1) Institutions of higher education that award baccalaureate degrees; (2) employer organizations; or (3) labor organizations.

Requirements

To achieve the purposes of section 207 of Perkins III, we propose to establish the following requirements. These requirements would apply to all applicants seeking funding under this competition.

(1) Each applicant must submit a signed Consortium Agreement (Agreement), providing evidence that each of the categories of membership required under Section 207 has been satisfied, and that each of the required members is eligible for membership

under the provisions of Perkins III. The Agreement must contain a signature of commitment from any participating secondary school, community college, and business member, affirming that those entities have formed a consortium to develop, implement and sustain a TPDP project as described under Section 207 of Perkins III. The Agreement Also must describe the roles and responsibilities of each consortium member within the proposed project. The format for the Agreement will be included in the Notice Inviting Applications.

(2) Each applicant must submit enrollment goals for the number of students in each student cohort to be enrolled in each year of the TPDP project.

(3) Each applicant must provide an assurance that it will enroll its first student cohort and begin classes no later than September of the calendar year after the year in which the grant award is made, and enroll its second, third, and fourth student cohorts by September of each subsequent year of the proposed project.

(4) Each applicant must submit a complete Proposed Project Course Sequence Plan (''the Plan'') to demonstrate how the proposed instructional program represents a sequential, four-year program of study that meets the specific criteria set forth in sections 202(a)(3) and 204(c) of Perkins III. The Plan must list the course sequences for each program of study within the proposed TPDP project, describing the specific academic and technical coursework required for all four years of the program. The Plan also must summarize program entrance requirements and specify the associate degree or postsecondary certificate to be earned upon completion of the program. The format for the Plan will be included in the Notice Inviting Applications.

(5) Each TPDP-funded project must involve a secondary school physically located on the site of a community college and provide a complete program of academic and technical coursework at the community college that, at a minimum, meets State requirements for high school graduation. Students must be enrolled full-time in the high school on the community college campus. However, enrolled students may participate in extra curricular activities at their original high school. Proposed projects that involve only the ''virtual'' location of a secondary school on the site of a community college, and projects that involve only satellite community college sites located on the premises of secondary schools, are not eligible for support under this competition.

(6) Each TPDP-funded project must carry out an evaluation to determine the impact of the project on a comprehensive set of student outcomes, including: Academic and technical skills achievement; high school graduation; enrollment and completion of postsecondary education; postsecondary remedial coursework; and labor market entry. In conducting this evaluation, each TPDP project must use either an experimental design, in which students are randomly assigned to the demonstration program or another program, or a quasi-experimental design, in which each program participant is matched with a non-participant possessing similar pre-program characteristics, such as test scores on State academic assessments, grade point average, class rank, technical coursework or course of study, and Socioeconomic status.

(7) Each TPDP project must submit annual reports of anticipated enrollment. The reports of anticipated enrollment must include the number of students in each cohort enrolled for the coming year and, if that differs from the enrollment goals stated in the approved application, the reasons. The reports of anticipated enrollment will be due at the end of April of each project year.

(8) Each TPDP project must submit annual project performance reports and a final project performance report.

Both the annual and final performance reports must summarize the TPDP project's progress and significant accomplishments, both with respect to the process of implementation and the outcomes of student participation; provide data regarding enrollment, persistence, and program completion for each student cohort; identify barriers to continued progress and outline solutions; include a progress report on and an analysis of the findings of the project evaluation; and review prospects for sustained operations after the cessation of Federal support. The annual and final performance reports will be due within 90 days of the end of each project year or of the end of the project.

Funded projects would be required to comply with all requirements adopted in the Notice of final requirements, priorities, and selection criteria to be published in the **Federal Register**. Failure to comply with any applicable program requirement may subject a grantee to special conditions, withholding, or termination.

Selection Criteria

We propose to use the following selection criteria to evaluate applications for new grants under this competition. The maximum score for all of the following criteria is 100 points. The maximum score for each criterion and sub-criterion is indicated in parentheses.

(a) *Quality of the project design.* (40 points)

In determining the quality of the design of the proposed project, we consider the following factors:

(1) The extent to which the applicant demonstrates its readiness to implement a complete, career-oriented, 4-year program of study, as evidenced by a formal articulation agreement concerning the structure, content and sequence of all academic and technical courses to be offered in the proposed tech prep program and, if applicable, the conditions under which dual credit will be awarded. (8 points)

(2) The extent to which the proposed instructional program will meet high academic standards that equal or exceed those established by the State. (4 points)

(3) The extent to which the applicant has aligned its secondary academic and technical course offerings and requirements for program completion with the entrance requirements for the corresponding postsecondary degree or certificate program. (4 points)

(4) The extent to which the applicant presents a detailed student recruitment plan that is likely to be effective in fulfilling the project's enrollment goals for each year of the project. (8 points)

(5) The extent to which the proposed project will provide comprehensive academic and career counseling and other support services to participating students at both the secondary and postsecondary levels, to ensure their persistence in the program and attainment of a postsecondary degree or certificate. (8 points)

(6) The extent to which the proposed project will provide high quality, sustained, and intensive professional development for instructors, counselors and administrators involved in the program. (8 points)

(b) *Quality of the management plan.* (15 points)

In determining the quality of the management plan for the proposed project, we consider the following factors:

(1) The extent to which the management plan outlines specific, measurable goals, objectives, and outcomes to be achieved by the proposed project. (5 points)

(2) The extent to which the management plan assigns responsibility

for the accomplishment of project tasks to specific project personnel, and provides timelines for the accomplishment of project tasks. (5 points)

(3) The extent to which the time commitments of the project director and other key personnel are appropriate and adequate to achieve the objectives of the proposed project. (5 points)

(c) *Quality of project personnel.* (15 points)

In determining the quality of project personnel, we consider the following factors:

(1) The extent to which the applicant encourages applications for employment from members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (5 points)

(2) The qualifications, including relevant training and experience, of the project director. (5 points)

(3) The qualifications, including relevant training and experience, of key project personnel, including teachers, counselors, administrators, and project consultants. (5 points)

(d) *Adequacy of resources.* (10 points)

In determining the adequacy of resources for the proposed project, we consider the following factors:

(1) The adequacy of support, including facilities, equipment, supplies, and other resources, from the participating institutions. (5 points)

(2) The extent to which the budget is adequate and costs are reasonable in relation to the objectives and design of the proposed project. (5 points)

(e) *Quality of the project evaluation.* (20 points)

In determining the quality of the evaluation, we consider the following factors:

(1) The extent to which the application presents a feasible, credible plan for project evaluation and includes: the type of design to be used; outcomes to be examined; and how participants will be assigned to the program or matched for comparison to non-program participants (10 points)

(2) The extent to which the evaluation will provide reports or other documents at appropriate intervals to be used for continuous program improvement. (4 points)

(3) The extent to which the proposed evaluation will be conducted by an independent evaluator with the necessary background and technical expertise to carry out the evaluation. (6 points)

Discussion of Priorities

Following the comment period, we will announce the final requirements, priorities, and selection criteria in a notice in the **Federal Register.** We will determine the final requirements, priorities and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use one or more of these proposed priorities, we invite applications through a notice in the **Federal Register**. When inviting applications we designate each priority as absolute, competitive preference, or invitational. The effect of each type of priority follows:

Absolute priority: Under an absolute priority we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority we give competitive preference to an application by either (1) awarding additional points, depending on how well or the extent to which the application meets the competitive preference priority (34 CFR 75.105(c)(2)(i); or (2) selecting an application that meets the competitive priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the invitational priority a competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Priorities

Proposed Priority 1

Under this proposed priority, we would give competitive preference by awarding up to 5 additional points to applications that require all teachers teaching core academic subjects to be highly qualified, as such term is defined by section 9101 (23) of the ESEA, as amended by NCLB. NOTE: ESEA defines core academic subjects as English, reading or language arts, mathematics, science, foreign languages, civics and government, economics, arts, history and geography.

Proposed Priority 2

Under this proposed priority, we would give competitive preference by awarding up to 5 additional points to applications that require each participating student, as a condition of high school graduation, to pass at least one high school level test (either a comprehensive test covering a variety of courses in a subject area or a high school end-of-course test) in English language arts, mathematics, and science. To receive any points under this priority, applicants must describe their specific high school graduation requirements.

Proposed Priority 3

Under this proposed priority, we would give competitive preference by awarding up to 5 additional points to applications that offer the proposed TPDP project as an alternative for students attending secondary schools that have been identified for school improvement under section 1116(b)(1) of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001; or include the proposed TPDP project in a corrective action or restructuring plan to improve student academic achievement at secondary schools identified for school improvement under section 116 of the ESEA. To receive any points under this priority, applicants must provide evidence of a school's designation under section 1116 of the ESEA.

Project Period

We have concluded that funding multi-year projects for a project period of five years entirely from the Fiscal Year 2002 appropriation will be necessary for TPDP grantees to fully meet the statutory purposes of Section 207 and the requirements of this notice. Such a funding arrangement will enable projects to engage in an adequate recruitment effort to meet their enrollment goals, and implement both the full, two-year secondary component and the full, two-year postsecondary component of the TPDP project for the first student cohort during the grant award period.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Applicable Program Regulations: 34 CFR parts 74–79.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register,** in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.* Catalog of Federal Domestic Assistance Number: 84.353.

Program Authority: 20 U.S.C. 2328.

Dated: January 22, 2003.

Carol D'Amico,

Assistant Secretary for Vocational and Adult Education.

[FR Doc. 03–1791 Filed 1–23–03; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Agency Information Collection Under Review by the Office of Management and Budget (OMB)

AGENCY: Department of Energy.

ACTION: Submission for OMB review, comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection package to the OMB for renewal under the Paperwork Reduction Act of 1995. The package requests a 3-year extension of its affiliated sources information collection, OMB control number 1910–5111. This information collection package covers collection of information necessary to provide the contracting officer with complete information on potential organizational conflicts involved in teaming arrangements. Departmental management uses the information to exercise management oversight regarding the implementation of applicable statutory and regulatory requirements and obligations. The collection of this information is critical to ensure that the Government has sufficient information to judge the degree to which awardees meet the terms of their agreements and ensure that improper organization conflicts are not created.

DATES: Comments regarding the information collection package should be submitted to the OMB Desk Officer at the following address no later than February 24, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the OMB Desk Officer of your intention to do so as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also notify the DOE contact listed in this notice.)

ADDRESSES: Address comments to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street, NW., Washington, DC 20503. Comments should also be addressed to Susan L. Frey, Director, Records Management Division, IM–11/Germantown Bldg., Office of Business and Information Management, Office of the Chief Information Officer, U.S. Department of Energy, 1000 Independence Ave, SW, Washington, DC 20585–1290.

SUPPLEMENTARY INFORMATION: This package contains (1) *OMB Control No.* 1910–5111 (2) *Package Title:* Purchasing by DOE Management and Operating Contractors from Contractor Affiliated Sources; (3) *Type of Respondents:* DOE Management and Operating Contractors; (4) *Estimated Number of responses:* 20; (5) *Estimated Total Burden Hours:* 100; (6) *Purpose:* This information is required by the Department to ensure that programmatic and administrative management requirements and resources are managed efficiently and effectively. The package contains 1 information and/or recordkeeping requirement, that is, the provision found at 48 CFR 952.209–8, Organizational Conflicts of Interest Disclosure—Advisory and Assistance Services.

Statutory Authority: Sec. 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

Issued in Washington, DC, on January 17, 2003.

Susan L. Frey,

Director, Records Management Division, Office of Business and Information Management, Office of the Chief Information Officer.

[FR Doc. 03–1639 Filed 1–23–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Under Review by the Office of Management and Budget (OMB)

AGENCY: Department of Energy.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection package to OMB for renewal under the Paperwork Reduction Act of 1995. The package requests a 3-year extension of its reporting and record keeping requirements for the Make-or-Buy Plans, OMB Control Number 1910–5102. This information is required by the Department to ensure whether DOE's management and operating contractors are subcontracting in the most cost-effective and efficient manner.

DATES: Comments regarding the information collection package should be submitted to the OMB Desk Officer no later than February 24, 2003. If you anticipate submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the OMB Desk Officer of your intention to do so as soon as possible. The Desk Officer may be telephoned at (202) 395–3087.

ADDRESSES: Address comments to DOE Desk Officer, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503. Comments should also be addressed to Susan L. Frey, Director, Records Management Division, Office of Business and Information Management, Office of the Chief Information Officer, IM–11/Germantown Bldg., U.S. Department of Energy, Washington, DC 20585–1290, or E-mail *susan.frey@hq.doe.gov*. (Also notify Irma Brown, Office of Procurement and Assistance Policy (ME–62), Washington, DC 20585 or E-mail *irma.brown@hq.doe.gov*).

SUPPLEMENTARY INFORMATION: The package contains (1) *Title:* Make-or-Buy Plans; (2) *Current OMB Control Number:* 1910–5102; (3) *Type of Respondents:* DOE management and operating contractors and offsite contractors; (4) *Estimated Number of Responses:* 36; (5) *Estimated Total Burden Hours:* 7,800, including record keeping hours, required to provide the information; (6) *Purpose:* This information is required by the Department to ensure whether DOE's management and operating contractors are subcontracting in the most cost-effective and efficient manner and to exercise management and oversight of DOE contractors; (7)

Number of Collections: The package contains 1 information and/or record keeping requirement.

Statutory Authority: Sec. 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

Issued in Washington, DC on January 17, 2003.

Susan L. Frey,

Director, Records Management Division, Office of Records and Business Management, Office of the Chief Information Officer.

[FR Doc. 03–1640 Filed 1–23–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket Nos. EA–247–A and EA–248–A]

Application to Export Electric Energy; Constellation NewEnergy, Inc.

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of Application.

SUMMARY: Under two separate applications, Constellation NewEnergy, Inc. (Constellation) has applied for authority to transmit electric energy from the United States to Mexico and from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before February 24, 2003.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Import/Export (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Rosalind Carter (Program Office) 202–586–7983 or Michael Skinker (Program Attorney) 202–586–6667.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On November 8, 2002, the Office of Fossil Energy (FE) of the Department of Energy (DOE) received two separate applications from Constellation for authorization to transmit electric energy from the United States to Mexico and from the United States to Canada. Constellation is a Delaware corporation and a wholly-owned subsidiary of Constellation Energy Group, Inc., a public utility holding company. Constellation is engaged in the marketing of electric energy and power at wholesale and retail throughout North America. Constellation does not own or control any facilities used for the generation, transmission, or distribution of electric energy nor does it have a franchised electric power service area. Constellation will purchase the power to be exported from electric utilities and federal power marketing agencies within the United States.

In FE Docket No. EA–247–A, Constellation NewEnergy proposes to export electric energy to Mexico and to arrange for the delivery of those exports to Mexico over the international transmission facilities owned by San Diego Gas and Electric Company, El Paso Electric Company, Central Power and Light Company, and Comision Federal de Electricidad, the national utility of Mexico. In FE Docket No. EA–248–A, Constellation NewEnergy proposes to export electric energy to Canada and to arrange for the delivery of those exports to Canada over the international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Citizens Utilities, Eastern Maine Electric Cooperative, International Transmission Company, Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power Cooperative, New York Power Authority, Niagara Mohawk Power Corporation, Northern States Power, and Vermont Electric Transmission Company.

The construction of each of the international transmission facilities to be utilized by Constellation NewEnergy, as more fully described in the applications, has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

On November 13, 2001, and on November 26, 2001, FE issued Order Nos. EA–247 and EA–248, granting AES New Energy, Inc. authority to export electric energy to Mexico and to Canada, respectively. As a result of a change in the upstream corporate ownership of AES New Energy, Inc. and a subsequent name change to Constellation, the subject applications have been submitted so that export authority may be obtained in the name of the new corporate entity.

Procedural Matters

Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to these applications should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the Constellation applications to export electric energy to Mexico and/or Canada should be clearly marked with Docket EA–247–A and/or Docket EA–248–A, respectively. Additional copies are to be filed directly with Cathy Barron, Constellation NewEnergy, Inc., 535 Boylston Street, Top Floor, Boston, Massachusetts 02116 *AND* R. Michael Sweeney, Jr., Troutman Sanders LLP, 401 9th Street, NW., Ste. 1000, Washington, DC 20004.

A final decision will be made on these applications after the environmental impacts have been evaluated pursuant to the National Environmental Policy Act of 1969, and a determination is made by the DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of these applications will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov.* Upon reaching the Fossil Energy Home page, select ''Regulatory Programs,'' then ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on January 17, 2003.

Anthony J. Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Import/Export, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 03–1642 Filed 1–23–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meeting be announced in the **Federal Register**.

DATES: Wednesday, February 12, 2003, 6 p.m.

ADDRESSES: DOE Information Center, 475 Oak Ridge Turnpike, Oak Ridge, TN.

FOR FURTHER INFORMATION CONTACT: Pat Halsey, Federal Coordinator, Department of Energy Oak Ridge Operations Office, PO Box 2001, EM–90, Oak Ridge, TN 37831. Phone (865) 576–4025; Fax (865) 576–5333 or e-mail: *halseypj@oro.doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

• The meeting will focus on long-term stewardship issues at the Oak Ridge Reservation. Lorene Sigal, a former Oak Ridge SSAB member, will give a brief history of the evolution of stewardship issues, an overview of current Oak Ridge SSAB stewardship activities, and a summary of national initiatives.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Pat Halsey at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes of this meeting will be available for public review and copying at the Department of Energy's Information Center at 475 Oak Ridge Turnpike, Oak Ridge, TN between 8 a.m. and 5 p.m. Monday through Friday, or by writing to Pat Halsey, Department of Energy Oak Ridge Operations Office, PO Box 2001, EM–90, Oak Ridge, TN 37831, or by calling her at (865) 576–4025.

Issued at Washington, DC on January 21, 2003.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 03–1641 Filed 1–23–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 400–038]

Willard Janke v. Public Service Company of Colorado; Notice Granting Extension of Time to File Answer to Complaint

January 17, 2003.

On January 3, 2003, notice was issued of Willard Janke's complaint against the Public Service Company of Colorado (Public Service), the licensee for the Tacoma-Ames Project No. 400. The notice established January 21, 2003, as the deadline for filing the answer to the complaint.

On January 15, 2003, Public Service filed a motion requesting an extension to January 24, 2003, of the deadline for filing its answer. Public Service has shown good cause for granting the extension. Accordingly, its request is granted and its answer must be filed on or before January 24, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1615 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 516]

South Carolina Electric & Gas Company; Notice of Meeting to Discuss Construction Status for Saluda Dam

January 17, 2003.

The Federal Energy Regulatory Commission (FERC) will hold an informational meeting to discuss ongoing construction activities and scheduling for the Saluda Seismic Remediation Project, FERC No. 516. The Saluda Project is located on the Saluda River in Richland, Lexington, Saluda, and Newberry counties, near Columbia, South Carolina.

South Carolina Electric & Gas Company (SCE&G) issued the contract for construction on August 12, 2002 to Barnard Construction Company. Mobilization of construction equipment and site preparation work has started. Work, including installation of a complex dewatering system, is underway with a considerable number of wells installed. Many other construction activities are ongoing.

The informational meeting will take place on February 6, 2003 from 6–8:30 p.m. at the Embassy Suites Hotel, Columbia-Greystone, 200 Stoneridge Drive, Columbia, SC 29210. FERC and SCE&G staff will discuss ongoing activities and schedule and respond to questions.

Please direct any questions about this meeting to Constantine G. Tjoumas at (202) 502–6734.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1616 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–135–000]

Williams Gas Pipelines Central, Inc.; Notice of Technical Conference

January 17, 2003.

In the Commission's order issued on December 31, 2002,[1] in the above-captioned docket, the Commission directed that a technical conference be held to address certain issues, as set forth in the Commission's order.

Take notice that the technical conference will be held on Tuesday, February 11, 2003, at 10 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

All interested parties and Staff are invited to attend.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1619 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG03–35–000, et al.]

AEG Operations. LLC., et al.; Electric Rate and Corporate Filings

January 16, 2003

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. AEG Operations, LLC

[Docket No. EG03–35–000]

Take notice that on January 10, 2003, AEG Operations, LLC (AEG Operations)

[1] Williams Gas Pipelines Central, Inc., 101 FERC 61,407 (2002).

filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

AEG Operations will operate and maintain the electric generating facility (the Facility) owned and currently operated by Mirant Neenah, LLC (Mirant Neenah). The Facility's entire output currently is sold on a long-term basis to a third party not affiliated with the Applicant. The Mirant Neenah Facility is located at Neenah, Wisconsin, and comprises two gas-fired turbine generators rated at 309 MW total generating capacity. AEG Operations' principal business offices are located at One Mid-America Plaza, Suite 518, Oakbrook Terrace, Illinois, 60181–4705.

Comment Date: February 6, 2003.

2. PacifiCorp

[Docket No. ER03–410–000]

Take notice that on January 14, 2003, PacifiCorp, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations Amendment No. 2 to the Power Marketing and Resource Management Service Agreement with Deseret Generation & Transmission Co-Operative.

PacifiCorp states that copies of this filing were supplied to the Utah Public Service Commission and the Public Utility Commission of Oregon.

Comment Date: February 4, 2003.

3. Arizona Public Service Company, El Paso Electric Company, Public Service Company of New Mexico, and Southern California Edison Company; Filing of Funding Agreement

[Docket No. ER03–411–000]

Take notice that on January 14, 2003, Arizona Public Service Company, El Paso Electric Company, Public Service Company of New Mexico, and Southern California Edison Company tendered for filing a Funding Agreement for the design, engineering and construction services associated with the facilities necessary to interconnect the Rudd Transmission Line to the ANPP High Voltage Switchyard between the Rudd Line Participants and Salt River Project Agricultural Improvement and Power District, as Operating Agent for the ANPP Switchyard Participants.

Comment Date: February 4, 2003.

4. Florida Power & Light Company

[Docket No. ER03–412–000]

Take notice that on January 14, 2003 Florida Power & Light Company (FPL) tendered for filing a Notice of Termination of an Interconnection & Operation Agreement (IOA) between FPL and Duke Energy Fort Pierce, LLC (Duke Energy). Termination of the IOA has been mutually agreed to by FPL and Duke Energy. FPL requests that the termination be made effective December 23, 2002.

Comment Date: February 4, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov*, using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866)208–3676, or for TTY, contact (202)502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1620 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2232–428—North Carolina and South Carolina]

Duke Energy Corporation; Notice of Availability of Draft Environmental Assessment

January 17, 2003.

In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Energy Regulatory Commission's (Commission) regulations (18 CFR part 380), Commission staff have reviewed a proposed Revised Shoreline Management Plan (SMP) for the Catawba-Wateree Project (FERC No. 2232), and have prepared a draft Environmental Assessment on the proposed plan. The project is located on the Catawba River in North Carolina and South Carolina.

Specifically, the project licensee (Duke Energy Corporation) has requested Commission approval of the SMP. The proposed SMP is intended to supercede the approved SMP including the classification maps. The draft EA addresses proposed revisions to SMP for the Catawba-Wateree Project. The SMP and maps address the allowable uses of 1,727 miles of shoreline for the 11 project reservoirs located in North Carolina and South Carolina. In the draft EA, Commission staff have analyzed the probable environmental effects of implementing the proposed SMP and have concluded that approval of the proposed SMP, with appropriate environmental measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

Copies of the draft EA are available for review in Public Reference Room 2-A of the Commission's offices at 888 First Street, NE., Washington, DC. The draft EA also may be viewed on the Commission's Internet Web site (*http://www.ferc.gov*) using the ''FERRIS'' link. Additional information about the project is available from the Commission's Office of External Affairs, at (202) 502–6088 or on the Commission's Web site using the FERRIS link. Click on the FERRIS link, enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance with FERRIS, contact *FERCOnlineSupport@ferc.gov* or call toll-free at (866) 208–3676, or for TTY contact (202) 502–8659. The FERRIS link on the FERC's Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

Any comments on the draft EA should be filed within 30 days of the date of this notice and should be addressed to Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please reference ''Catawba-Wateree Hydroelectric Project, FERC Project No. 2232–428'' on all comments. 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 under the ''e-Filing'' link.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1617 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

January 17, 2003.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications recently received in the Office of the Secretary. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866)208–3676, or for TTY, contact (202)502–8659.

EXEMPT

Docket No.	Date filed	Presenter or requester
1. Project Nos. 2897–000, 2931–000, 2932–000, 2941–000, 2942–000	1–06–03	Dana Paul Murch.
2. Project No. 1927–000	1–13–03	James A. Caplan.
3. Project No. 719–000	1–13–03	Reid R. Brown.
4. Project No. 2574–032	1–13–03	Pat Weslowski.
5. CP02–396–000	1–13–03	Garland Pardue.
6. Project Nos. 20–000, 472–000, 2401–000	1–13–03	Susan Giannettino.
7. Project No. 719–007	1–17–03	Charles Hall.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1618 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–2001–000]

Electric Quarterly Reports; Revised Public Utility Filing Requirements Docket No. RM01–8–000; Notice of Extension of Time

January 17, 2003.

On December 19, 2002, the Commission issued Order 2001–C, specifying details about the requirement for utilities to file a list of conforming contracts (as mandated in Order 2001) and requiring future Electric Quarterly Reports to be filed using the new Electric Quarterly Report Submission Software. Both the list of conforming contracts and the fourth quarter Electric Quarterly Report are due to be filed on or before January 31, 2003.

Numerous filers have requested an extension of time in order to compile the required data and adjust to the new software requirements. In consideration of this situation, notice is hereby given that the time to file the list of conforming contracts and the fourth quarter 2002 Electric Quarterly Report is extended to and including February 14, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–1614 Filed 1–23–03; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2003–0006, FRL–7441–3]

Agency Information Collection Activities: Proposed Collection; Comment Request; Mobile Source Emission Factor On-Highway Recruitment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): Mobile Source Emission Factor On-Highway Recruitment (OMB Control No. 2060–0078; EPA ICR No. 0619.10) expiring 06/30/2003. Before submitting the ICR to OMB for review and approval, EPA

is soliciting comments on specific aspects of the proposed information collection as described below. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before March 25, 2003.

ADDRESSES: Follow the detailed instructions in the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Carl Scarbro, Assessment and Standards Division, Office of Transportation and Air Quality, AATC, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 734–214–4209; fax number: 734–214–4939; e-mail address: *scarbro.carl@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OAR–2003–0006, which is available for public viewing at the Office of Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 60 days of this notice, and according to the following detailed instructions: Submit your comments to EPA online using EDOCKET (our preferred method), by e-mail to *a-and-r-docket@epamail.epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *www.epa.gov./edocket.*

Affected entities: Entities potentially affected by this action are owners of on-highway vehicles.

Title: Mobile Source Emission Factor On-Highway Recruitment (OMB Control No. 2060–0078; EPA ICR No. 0619.10) expiring 06/30/2003.

Abstract: The EPA Emission Inventory Group, through contractors, solicits the general public to voluntarily offer their vehicle for emissions testing. There are two methods used to solicit the general public for participation in Emission Factors Program (EFP):

1. Postal cards are sent to a random selection of vehicle owners using State motor vehicle registration lists; and

2. A random selection of motor vehicle owners, who arrive at State inspection stations on an annual or biennial schedule, are solicited.

The legislative basis for the Emission Factors Program is section 103(a)(1)(2)(3) of the Clean Air Act, which requires the Administrator to ''conduct * * * research, investigations, experiments, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, and control of air pollution'' and ''conduct investigations and research and make surveys concerning any specific problem of air pollution in cooperation with any air pollution control agency * * *''

EPA uses the data from the EFP to verify predictions of the computer model known as MOBILE, which calculates the contribution of mobile source emissions to ambient air pollution. MOBILE is used by EPA, state and local air pollution agencies, the automotive industry, and other parties that are interested in estimating mobile source emissions. These estimates, when generated by governments are the basis for State Implementation Plans (SIPs), and Reasonable Further Progress (RFP) reports for the attainment status assessments for the National Ambient Air Quality Standards (NAAQS).

Furthermore, the EFP data collected under this ICR will be used to construct a new model to replace MOBILE, the ''Multi-scale Motor Vehicle & Equipment Emission System'' (MOVES). MOVES will be based on field sample data as opposed to laboratory simulations. This change is due to recommendations made to EPA by the National Research Council, the Office of Management and Budget and is enabled by the availability of suitable technology for the collection of emission and activity data while the vehicles are being used by their owners/operators. 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 EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden Statement: Public reporting burden for this collection of information is estimated to average 10 minutes to 2 hours per response, including the time for reviewing instructions, delivering the vehicle for testing, installing or uninstalling field sampling equipment on the vehicle, or in some instance filling out a travel log. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and

providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: January 16, 2003.

Carl A. Scarbro,

Environmental Protection Specialist, Office of Air and Radiation, Office of Transportation and Air Quality, Assessment and Standards Division, Air Toxics Center.

[FR Doc. 03–1625 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6636–9]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements filed January 13, 2003 through January 17, 2003, pursuant to 40 CFR 1506.9.

EIS No. 030023, Final EIS, FHW, OH, KY, Ironton-Russell Bridge Replacement Project, LAW–93C–0.00, PID 17359, Structurally-Deficient and Functionally-Obsolete Bridge Replacement, Funding, NPDES, U.S. Coast Guard Section 9 Bridge Permits and U.S. Army COE Section 10 and 404 Permits Issuance, Lawrence County, OH and Greenup County, KY, Wait Period Ends: February 24, 2003, Contact: Pete Jilek (614) 280–6835.

EIS No. 030024, Draft EIS, AFS, County Line-Fourmile Project, To Implement Management Direction as Outlined in the Allegheny National Forest Land and Resource Management Plan, Bradford Ranger District, Warren and McKean Counties, PA, Comment Period Ends: March 10, 2003, Contact: Jim Apgar (814) 362–4613.

EIS No. 030025, Draft EIS, AFS, ID, Upper Bear Timber Sale Project, Proposal to Reduce Fuels, Manage Forest Vegetation and Roads Management, Payette National Forest, Council Ranger District, Adams County, ID, Comment Period Ends: March 10, 2003, Contact: Mary Farnsworth (208) 253–0100.

EIS No. 030026, Final EIS, AFS, ID, Middle-Black Analysis Project, Proposes Vegetative Management, Watershed Restoration, and Noxious Weed Activities Aimed at Ecosystem Restoration, Clearwater National Forest, North Fork Ranger District, Clearwater County, ID, Wait Period Ends: February 24, 2003, Contact: Tam White (208) 476–8226.

EIS No. 030027, Final EIS, SFW, AK, Swanson River Satellites Natural Gas Exploration and Development Project, Evaluation of a Right-of-Way Permit Application and U.S. Army COE Section 404 and NPDES Permits Issuance, Kenai National Wildlife Refuge, Kenai Peninsula, AK, Wait Period Ends: February 24, 2003, Contact: Brian L. Anderson (907) 786–3379.

EIS No. 030028, Final EIS, FTA, FL, Tampa Rail Project, Transportation Improvements, Light Rail Transit (LRT) or Diesel Multiple Unit (DMU) Vehicles, City of Tampa, Hillsborough County, FL, Wait Period Ends: February 24, 2003, Contact: Derek R. Scott (404) 562–3524.

EIS No. 030029, Draft EIS, AFS, CA, Blue Fire Forest Recovery Project, Proposal to Move the Existing Condition Caused by the Blue Fire of 2001 Towards the Desired Condition, Modoc National Forest, Warner Mountain Ranger District, Lassen and Modoc Counties, CA, Comment Period Ends: March 10, 2003, Contact: Edith Asrow (530) 279–6116.

EIS No. 0230030, Draft EIS, NPS, AR, Arkansas Post National Memorial General Management Plan, Implementation, Osotouy Unit, Arkansas and Mississippi Rivers, Arkansas County, AR, Comment Period Ends: March 25, 2003, Contact: Nick Chevance (402) 221–7286.

EIS No. 030031, Draft EIS, JUS, CA, Juvenile Justice Facility and East County Hall of Justice, Proposal to Evaluates two Projects that could be Constructed at one (Combined Siting) or (Separate Siting), Alamenda County, CA, Comment Period Ends: March 10, 2003, Contact: Paul DeLameter (202) 514–7903.

Amended Notices

EIS No. 020511, Draft EIS, COE, MD, Aberdeen Proving Ground (APG) Project, To Conduct Research and Development, Test and Evaluate Ordnance, Military Equipment and to Train Personnel, Chesapeake Bay, Hartford, Baltimore, Kent and Cecil Counties, MD, Comment Period Ends: February 18, 2003, Contact: Tracy Dunne (410) 278–2479. Revision of FR Notice Published on 12/20/2002: CEQ Comment Period Ending 2/3/2003 has been Extended to 2/18/2003.

Dated: January 21, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–1621 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6637–1]

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 the **Federal Register** dated April 12, 2002 (67 FR 17992).

Draft EISs

ERP No. D–AFS–J65368–UT Rating LO, Duck Creek—Swains Access (Duck/Swains), Management Project, Wildlife Habitat, Soil and Watershed Conditions and Motorized Vehicle Use Management Improvements, Dixie National Forest, Cedar City Ranger District, Iron, Garfield and Kane Counties, UT.

Summary: EPA expressed lack of objections and fully supports closing excess, redundant and damaging roads with appropriate mitigation measures to decrease road density.

ERP No. D–AFS–L65406–ID Rating LO, North Kennedy-Cottonwood Stewardship Project, Existing Transportation System Modifications and Forest Health Improvements through Vegetation Management both Commercial and Non-Commercial Methods, Boise National Forest, Emmett Ranger District, Gem and Valley Counties, ID.

Summary: EPA expressed lack of objections with the proposed action. EPA suggested that additional information on the road closure/management and revegetation measures to improve habitat to meet Forest Plan Wildlife Recovery goals should be included in the Final EIS.

ERP No. D–COE–L36115–WA Rating EC2, Centralia Flood Damage Reduction Project, Chehalis River, Lewis and Thurston Counties, WA.

Summary: EPA expressed environmental concerns and

recommended that the Corps improve the Purpose and Need Statement, provide additional and/or revised alternatives, supply supportive information on environmental sustainability, disclose compliance with floodplain management (Executive Order 110998) and address approved flood maps, and address indirect and cumulative impacts for this proposed project.

ERP No. D–FRC–L05228–ID Rating NS, Bear River Hydroelectric Project, Application for a New License (Relicense) for Three Existing Hydroelectric Projects: Soda (FERC No. 20–019), Grace-Cove (FERC No. 2401–007) and Oneida (FERC No. 472–017), Bear River Basin, Caribou and Franklin Counties, ID.

Summary: EPA used a screening tool to conduct a limited review of the draft EIS. Based on the screen, EPA does not foresee having any environmental objections to the proposed project. Therefore, a detailed review of the draft EIS was not conducted.

ERP No. D–IBR–K39076–00 Rating EC2, Navajo Reservoir Operations, Operational Changes to Navajo Dam and Reservoir, Related Flow Recommendation, Implementation and Funding, Navajo Unit-San Juan River, NM, CO and UT.

Summary: EPA has environmental concerns with the long-term sustainability of additional water development in the Basin and urged an equitable balance of available water supplies, water supply commitments, and environmental needs. EPA strongly encouraged development of the Memorandum of Agreement to protect water released for endangered species from diversion by intervening appropriators. While EPA supports reoperation of Navajo Dam to implement the Flow Recommendations, EPA has concerns regarding water quality, mitigation, indirect and cumulative impacts, monitoring and the adaptive management plan.

ERP No. D–NOA–K91011–00 Rating EC2, 2003 Pacific Coast Groundfish Fishery, Groundfish Acceptable Biological Catch and Optimum Yield Specifications and Management Measures, Implementation, WA, OR and CA.

Summary: EPA has environmental concerns based on insufficient information on stock rebuilding, enforcement of harvest measures, relationship between federal and state groundfish fisheries, trawl vessels exemptions, indirect impacts and tribal fishing rights.

ERP No. D–SFW–K64022–CA Rating EC2, Aquatic Habitat Conservation Plan and Candidate Conservation Agreement with Assurances to Conserve Habitat for and Mitigate Impacts on Six Aquatic Species, USFWS Enhancement of Survival Permit and an USMFS Incidental Take Permit Issuance, Humboldt and Del Norte Counties, CA.

Summary: EPA commended the approach of developing a comprehensive aquatic management strategy to address potential impacts to listed and potentially listed fish and amphibian species, but expressed specific environmental concerns related to water temperature impacts.

ERP No. D–USN–K52004–CA Rating EC2, Advanced Amphibious Assault Vehicle (AAAV) Development, Replacement and Establishment, Implementation, Del Mar Basin Area of Marine Base Corps (MCB) Camp Pendelton, San Diego County, CA.

Summary: EPA expressed environmental concerns, noting that additional mitigation may be available to potentially reduce the project's environmental impacts, including impacts to (non-ocean) surface water quality and air quality.

ERP No. DA–FAA–E40785–FL Rating EC2, Fort Lauderdale-Hollywood International Airport, Runway 9R–2FL Expansion and other Associated Improvements, New Information concerning the Predicted Number of Residents Impacted by Noise for Alternatives using 2000 Census Block Data or Field Inspection, Funding, Broward County, FL.

Summary: EPA continues to have environmental concerns with noise regarding the residences located south of the runway proposed for extension. Additional mitigation through residential acquisition over time was requested.

Final EISs

ERP No. F–COE–K39073–CA, Middle Creek Flood Damage Reduction and Ecosystem Restoration Project located between Highway 20 and Middle Creek immediately northwest of Clear Lake, Implementation, Lake County, CA.

Summary: EPA reviewed the EIS and found that the document adequately addresses the issues raised in our comment letter on the DEIS.

ERP No. F–IBR–K31003–CA, Imperial Irrigation District Water Conservation and Transfer Project and Draft Habitat Conservation Plan (HCP), Implementation and U.S. Fish and Wildlife Service Section 10 Incidental Take Permit Approval and Issuance, Colorado River, Imperial County, CA.

Summary: EPA continues to have environmental objections to the potential adverse impacts on surface and groundwater quality, air quality and biological resources and believes these objections could be addressed by the new proposed Habitat Conservation Plan and the Salton Sea Restoration Project.

ERP No. F–IBR–K39072–00, Implementation Agreement (IA), Inadvertent Overrun and Payback Policy (IOP) and Related Federal Actions, Implementation, Quantification Settlement Agreement (QSA), Lower Colorado River, in the States of AZ, CA and NV.

Summary: EPA continues to have environmental concern with the potential cumulative impacts on water quality constituents in drinking water sources and cumulative impacts on Indian Trust assets. EPA believes these concerns could be addressed by the new proposed Habitat Conservation Plan and the Salton Sea Restoration Project.

ERP No. F–NAS–A12043–00, PROGRAMMATIC—MARS Exploration Rover—2003 (MER–2003) Project, Continuing the Long-Term Exploration of MARS, Implementation.

Summary: EPA has no objection to the proposed action.

Dated: January 21, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–1622 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7442–6]

Clean Air Scientific Advisory Committee, Notification of Public Advisory Committee Meeting; Teleconference Consultation on Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants

ACTION: EPA Clean Air Scientific Advisory Committee, Notification of Public Advisory Committee Meeting; Teleconference Consultation on Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), Public Law 92–463, notice is hereby given that the Clean Air Scientific Advisory Committee (CASAC) of the U.S. Environmental Protection Agency's (EPA or Agency) Science Advisory Board (SAB) will meet via teleconference on Thursday, February 6,

2003, from 10 a.m. to 1 p.m. eastern time. This teleconference meeting will be hosted out of Conference Room 6013, U.S. EPA, Ariel Rios Federal Building North, 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The meeting is open to the public; however, due to limited space, seating will be on a first-come basis. The public may also attend via telephone, however, lines may be limited. Information on how to participate is provided below.

Purpose of this Meeting: The purpose of this public teleconference meeting is for the CASAC to conduct a consultation with EPA on the Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants. (*Note:* A full CASAC review of the first revised draft AQCD for ozone and related photochemical oxidants is scheduled to take place later this calendar year, and will be announced via a separate **Federal Register** notice.)

Background: EPA promulgates National Ambient Air Quality Standards (NAAQS) based on scientific information assessed in air quality criteria documents (AQCD) issued under the Clean Air Act (CAA), section 108. The CAA also requires periodic (*i.e.*, every five years) revision of criteria and review of NAAQS. Furthermore, section 109 of the CAA directed the establishment of the CASAC (42 U.S.C. 7409). The CASAC has a statutorily-mandated responsibility under the CAA to review and offer scientific and technical advice to the EPA Administrator on the air-quality criteria and regulatory documents which form the basis for the NAAQS. The previous AQCD for ozone, published in July 1996, provided the scientific basis for EPA's promulgation, in July 1997, of a new eight-hour NAAQS for ground-level ozone.

The Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants was prepared by EPA's Office of Research and Development (ORD) National Center for Environmental Assessment (NCEA), located at Research Triangle Park (RTP), NC. The plan presents information on EPA's approach to assessing the latest available scientific information to be incorporated into a revised Ozone AQCD, identifies key issues to be addressed in the Ozone AQCD, and includes brief summaries of legislative requirements and the history of previous ozone criteria revisions and NAAQS reviews. ORD will prepare a draft revised Ozone AQCD and subject it to review at expert peer-review workshops, by the public, and by the CASAC.

The main purpose of the forthcoming revised AQCD for Ozone and Related Photochemical Oxidants is to critically evaluate and assess the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of these pollutants in the ambient air. ORD will place emphasis on assessment of health and environmental effects information. Other scientific information will also be evaluated, in part to provide a better understanding of key issues such as those associated with ozone photochemistry; issues on environmental ozone concentrations attributable to anthropogenic and background sources; and issues related to the health and environmental effects associated with changes in solar UV radiation and global warming, as mediated by changes in tropospheric ozone. The final Ozone AQCD document will be used by EPA's Office of Air Quality Planning and Standards (OAQPS) in its review of the Ozone NAAQS.

FOR FURTHER INFORMATION CONTACT: To participate in this meeting, contact Mr. Fred Butterfield, CASAC Designated Federal Officer, U.S. EPA Science Advisory Board (1400A), Suite 6450CC, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone/voice mail at (202) 564–4561; fax at (202) 501–0582; or via e-mail at: *butterfield.fred@epa.gov.* Members of the public desiring additional information about the meeting locations or the call-in number for the teleconference must contact Mr. Butterfield at the addresses and numbers identified above.

Submitting Public Comments: The CASAC will make a brief period of time available during the teleconference meeting to take public comments on the subject of the consultation. This oral public comment period will be no more than 15 minutes in length and will be divided among all speakers who register in advance. Registration is on a first-come basis. Speakers who have been granted time on the agenda may not yield their time to other speakers. Those wishing to speak but who are unable to register in time may provide their comments in writing. Requests for oral comments must be in writing (e-mail, fax or mail) and received by Mr. Butterfield at the address above no later than noon eastern time on February 4, 2003.

Availability of Review Material: There is only one document that is the subject of the CASAC consultation: NCEA's Project Work Plan for Revised Air Quality Criteria for Ozone and Related Photochemical Oxidants. This document is available electronically at the following URL address: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55125.* For information and any questions pertaining to the review document, please contact Mr. James Raub, NCEA-RTP, via telephone: (919) 541–4157; fax: 919–541–1818; or e-mail: *raub.james@epa.gov.*

Providing Oral or Written Comments: 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. Specific instructions are as follows:

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 10 minutes (unless otherwise indicated above). For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than 15 minutes total (unless otherwise indicated above). Deadlines for getting on the public speaker list for a meeting are given above. Speakers who plan to attend the teleconference meeting in person should bring at least 25 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, written comments are requested to be provided so that they will be received in the SAB Staff Office at least one week prior to the meeting date, in order for the comments to be made available to the reviewers at the meeting for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above, as follows: one hard copy with original signature and one electronic copy via e-mail (acceptable file formats: Adobe Acrobat [.pdf], WordPerfect or MS Word). Those providing written comments who also attend the meeting are requested to bring 25 copies of their comments for public distribution.

Meeting Access: Individuals requiring special accommodations at this meeting, including wheelchair access to the conference room, should contact Mr. Butterfield at least five business days prior to the meeting (*i.e.*, by Thursday, January 30) so that appropriate arrangements can be made.

General Information: The SAB was statutorily-established in 1978 (42 U.S.C. 4365) to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. Additional information concerning the EPA Science Advisory Board, including its structure, function, and composition, may be found on the EPA SAB Web site at: *http://www.epa.gov/sab;* and in the EPA Science Advisory Board FY2001 Annual Staff Report, which is available from the EPA SAB Publications Staff at phone: (202) 564–4533; via fax at: (202) 501–0256; or on the SAB Web site at: *http://www.epa.gov/sab/annreport01.pdf.*

Dated: January 16, 2003.

A. Robert Flaak,

Acting Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 03–1628 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7442–7]

Good Neighbor Environmental Board Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: The next meeting of the Good Neighbor Environmental Board, a federal advisory committee that reports to the President and Congress on environmental and infrastructure projects along the U.S. border with Mexico, will take place in Washington, D.C. on February 18 and 19, 2003. It is open to the public.

DATES: On February 18, a special half-day session called ''Border Environmental Forecast 2003'' will begin at 9 a.m. (registration at 8:30 a.m.) and end at 12 noon, followed by the Board's Strategic Planning Session from 2 p.m to 5:30 p.m. On February 19, the Board will hold its routine business meeting from 8 a.m. to 12 noon. A pre-meeting orientation session for new members will take place from 4–6 p.m. on February 17.

ADDRESSES: The meeting site is the Hotel Washington located at the corner of 15th St. NW. and Pennsylvania Ave. (515 15th Street, NW., Pennsylvania Ave.) Washington, DC 20004.

The closest metro is Metro Center (on the Red Line).

FOR FURTHER INFORMATION CONTACT: Elaine M. Koerner, Designated Federal Officer for the Good Neighbor Environmental Board, Office of Cooperative Environmental Management, Office of the Administrator, USEPA, MC1601A, 1200 Pennsylvania Ave. NW., Washington, DC 20004, (415) 972–3437, *koerner.elaine@epa.gov.*

Meeting Access: Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the Designated Federal Officer at least five business days prior to the meeting so that appropriate arrangements can be made.

SUPPLEMENTARY INFORMATION: *Agenda:* The Border Environmental Forecast 2003 seminar is one of three activities scheduled for February 18 and 19. This three-hour expert Forecast seminar will begin at 9 a.m. (registration at 8:30 a.m.) and conclude at noon. In keeping with a similar session hosted last year, two panels of border-region experts will forecast the most pressing environmental challenges the border region will face in the year ahead. Immediately following the seminar, from 12 to 12:30 p.m. a public comment session will take place. During the afternoon of February 18, the Board will hold its annual Strategic Planning Session; a Road Map for the year ahead and criteria for measuring its effectiveness are among the products to be developed. The following morning, February 19, the Board will hold a routine business meeting. All of these activities are open to the public.

Public Attendance: The public is welcome to attend all portions of the meeting. Members of the public who plan to file written statements and/or make brief (suggested 5-minute limit) oral statements at the public comment session are encouraged to contact the Designated Federal Officer for the Board prior to the meeting.

Background: The Good Neighbor Environmental Board meets three times each calendar year at different locations along the U.S.-Mexico border and also holds an annual strategic planning session. It was created by the Enterprise for the Americans Initiative Act of 1992. An Executive Order delegates implementing authority to the Administrator of EPA. The Board is responsible for providing advice to the President and the Congress on environmental and infrastructure issues and needs within the States contiguous to Mexico in order to improve the quality of life of persons residing on the United States side of the border. The statute calls for the Board to have representatives from U.S. Government agencies; the governments of the States of Arizona, California, New Mexico and Texas; and private organizations with expertise on environmental and infrastructure problems along the southwest border. The U.S. Environmental Protection Agency gives notice of this meeting of the Good Neighbor Environmental Board pursuant to the Federal Advisory Committee Act (Public Law 92–463).

Dated: January 13, 2003.

Oscar Carrillo,

Acting Designate Federal Officer.

[FR Doc. 03–1627 Filed 1–23–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

January 13, 2003.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 24, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *lesmith@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at *lesmith@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0387.

Title: On Site Verification of Field Disturbance Sensors—Section 15.201(d).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 200.

Estimated Time per Response: 18 hours.

Frequency of Response: Recordkeeping; one time and on occasion reporting requirement; third party disclosure.

Total Annual Burden: 3,600 hours.

Total Annual Cost: $40,000.

Needs and Uses: FCC rules permit the operation of field disturbance sensors in the low VHF region of the spectrum. To monitor non-licensed field disturbance sensors operating in the low VHF television bands, a unique procedure for on-site equipment testing of the systems is required to ensure suitable safeguards for the operation of these devices. Data are retained by the holder of the equipment authorized/issued by the FCC and made available only at the request of the Commission.

OMB Control Number: 3060–0436.

Title: Equipment Authorization—Cordless Telephone Security Coding.

Form Number: N/A.

Type of Review: Extension of currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents: 100.

Estimated Time Per Response: 1.5 hours.

Frequency of Response: Recordkeeping; one time and on-occasion reporting requirements; third party disclosure.

Total Annual Burden: 150 hours.

Total Annual Cost: None.

Needs and Uses: The FCC requires cordless telephone security features protect the public switched telephone network from unintentional line seizure and telephone dialing. These features prevent unauthorized access to the telephone line, the dialing of calls in response to signals other than those from the owner's handset, and the unintentional ringing of a cordless telephone handset. Use of the cordless telephone security features reduces the harm caused by some cordless telephones to the ''911'' Emergency Service Telephone System and the telephone network in general.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–1655 Filed 1–23–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

January 14, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 24, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judith Boley Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *jboley@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith Boley Herman at 202–418–0214 or via the Internet at *jboley@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0798.

Title: FCC Application for Wireless Telecommunications Bureau Radio Service Authorization.

Form Nos.: FCC Form 601.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, state, local or tribal government.

Number of Respondents: 242,555.

Estimated Time Per Response: 1.25 hours.

Frequency of Response: On occasion and every 10 years reporting requirements, third party disclosure requirement, recordkeeping requirement.

Total Annual Burden: 212,235 hours.

Total Annual Cost: $48,510,000.

Needs and Uses: The FCC Form 601 is a consolidated, multi-part application form, or ''long form'' that is used for general market-based licensing and site-by-site licensing in the Wireless Telecommunications Radio (WTB) Services' Universal Licensing System (ULS). The FCC Form 601 is composed of a main form that contains the administrative information and a series of schedules used for filing technical information. Respondents are encourages to file electronically. The form has been modified to adopt requirements in various Commission rulemakings. Additionally, the Commission is increasing the number of respondents for potential winners to file in upcoming auctions, thus removing the need for repetitive emergency clearances submitted to OMB due to auction related changes (additional radio services necessary for auction winners).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–1656 Filed 1–23–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL HOUSING FINANCE BOARD

Sunshine Act Meeting Notice; Announcing an Open Meeting of the Board

TIME AND DATE: 3 p.m. Wednesday, January 29, 2003.

PLACE: Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

STATUS: The entire meeting will be open to the public.

MATTERS TO BE CONSIDERED:

- Rescission of Finance Board Resolutions Governing the Federal Home Loan Bank of Atlanta's Affordable Multifamily Participation Program.
- Community Investment Cash Advance—Approval of Claritas, Inc. as Data Source for Determining Area Median Incomes.
- Appointment of Federal Home Loan Bank Directors.
- Delegation of Authority.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

Arnold Intrater,

General Counsel

[FR Doc. 03–1778 Filed 1–22–03; 1:40 pm]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 02–06]

Hudson Shipping (Hong Kong) Ltd. D/B/A Hudson Express Lines; Possible Violations of Section 10(a)(1) of the Shipping Act of 1984; Notice of Amended Order of Investigation

On April 5, 2002, the Federal Maritime Commission (''Commission'') served an Order of Investigation and Hearing (''Order'') on Hudson Shipping (Hong Kong) Ltd. d/b/a Hudson Express Lines (''Hudson''), instituting a proceeding to determine whether Hudson violated section 10(a)(1) of the Shipping Act of 1984 (''Shipping Act'') and, in the event violations are found, whether penalties should be assessed and, if so, in what amount and whether a cease and desist order should be issued. Notice of the Order was published in the **Federal Register** on April 18, 2002 (67 FR 19185).

Notice is hereby given that on January 17, 2003, the Commission amended the Order to also determine whether Hudson violated section 19(b)(1) of the Shipping Act; whether, in the event violations of section 19(b)(1) of the Shipping Act are found, civil penalties should be assessed against Hudson and in what amount; and whether, in the event violations are found, an appropriate cease and desist order should be issued.

Any person having an interest in participating in this proceeding may file a petition for leave to intervene in accordance with Rule 72 of the Commission's rules of practice and procedure, 46 CFR 502.72.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–1590 Filed 1–23–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 10 a.m.—January 29, 2003.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: 1. Docket No. 02–02—Canaveral Port Authority—Possible Violations of Section 10(b)(10), Unreasonable Refusal to Deal or Negotiate.

CONTACT PERSON FOR MORE INFORMATION: Bryant L. VanBrakle, Secretary, (202) 523–5725.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–1790 Filed 1–22–03; 2:06 pm]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 18, 2003.

A. Federal Reserve Bank of Cleveland (Stephen J. Ong, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. McCreary National Bancorp, Inc., Corbin, Kentucky; to become a bank holding company by acquiring 100 percent of the voting shares of McCreary National Bank, Whitley City, Kentucky.

B. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Forest Merger Corporation and FBR TRS Holdings, Inc., both in Arlington, Virginia; to become bank holding companies by merging with Friedman, Billings, Ramsey Group, Inc., and FBR Asset Investment Corporation, both in Arlington, Virginia, and thereby indirectly acquiring FBR Bancorp, Inc., Arlington, Virginia, and FBR National Bank and Trust, Bethesda, Maryland. After the merger, Applicants would be renamed Friedman, Billings, Ramsey Group, Inc.

Applicants also have applied to acquire indirectly more than 5 percent of the voting shares of Bancorp Rhode Island, Inc., Providence, Rhode Island, and thereby indirectly acquire Bank Rhode Island, East Providence, Rhode Island; The Banc Corporation, Birmingham, Alabama, The Bank, Warrior, Alabama; and Pacific Union Bank, Los Angeles, California.

Board of Governors of the Federal Reserve System, January 17, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–1574 Filed 1–23–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C.

1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 6, 2003.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Bank One Corporation, Chicago, Illinois; to expand to not more than 15 percent of its total consolidated capital stock and surplus its investments in community development activities, pursuant to section 225.28(b)(12)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, January 17, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.03–1573 Filed 1–23–03; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards and Security.

Time and Date: 9 a.m. to 5 p.m., January 29, 2003; 9 a.m. to 1 p.m., January 30, 2003.

Place: Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue SW., Washington, DC.

Status: Open.

Purpose: The agenda for Wednesday, January 29th includes presentations from three panels (health care providers, health plans, and health researchers) on current coding practices for Complementary Alternative Medicine (CAM) services and therapies. The presentations and question and answer periods will be followed by a Roundtable discussion among the panelists. The morning session on the 30th will be an interactive discussion with industry representatives regarding ways to improve the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards maintenance and update process.

CONTACT PERSON FOR MORE INFORMATION:

Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Karen Trudel, Senior Technical Advisor, Security and Standards Group, Centers for Medicine and Medicaid Services, MS: C5–24–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, telephone: 410–786–9937; or Majorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone: (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/* where an agenda for the meeting will be posted when available.

Dated: January 14, 2003.

James Scanlon,

Acting Director, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 03–1606 Filed 1–23–03; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2177–PN]

RIN 0938–AM38

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Hospices

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for continued recognition as a national accreditation program for hospices that wish to participate in the Medicare or Medicaid programs. The Social Security Act requires that within 60 days of receipt of an organization's complete application, the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 24, 2003.

ADDRESSES: In commenting, please refer to file code CMS–2177–PN.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2177–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 (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: 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 Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO 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 $10. 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**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met. Section 1861 (dd)(1) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice program. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. In 42 CFR part 418, we specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospice care.

Generally, to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with our conditions or requirements. Following that certification, the hospice is subject to routine monitoring by a State survey agency to ensure continuing compliance. As an alternative to surveys by State agencies, section 1865(b)(1) of the Act provides that, if the Secretary finds that, through accreditation by a national accreditation body, a provider entity demonstrates that all of our applicable conditions and requirements are met or exceeded, the Secretary will deem that the provider entity has met the applicable Medicare requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, CMS shall ''deem'' those provider entities as having met the requirements. Section 1865(b)(2) of the Act further requires that the Secretary's findings concerning review and reapproval as a recognized accreditation program for hospices consider the reapplying accreditation organization's—

- Requirements for accreditation;
- Survey procedures;
- Ability to provide adequate resources for conducting required surveys;
- Ability to supply information for use in enforcement activities;
- Monitoring procedures for provider entities found out of compliance with the conditions or requirements; and
- Ability to provide the Secretary with necessary data for validation.

Section 1865(b)(3)(A) of the Act requires that the Secretary publish a notice within 60 days of receipt of a written request; the notice must—

- Identify the national accreditation body making the request;
- Describe the nature of the request; and
- Provide at least a 30-day public comment period.

In addition, we must publish a finding of approval or denial of the application within 210 days from the receipt of the completed request.

Our regulations concerning reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). Our regulations require accreditation organizations to reapply for continued approval of deeming authority every 6 years or sooner, as we determine.

JCAHO's term of approval as a recognized accreditation program for hospices expires June 18, 2003.

The purpose of this proposed notice is to inform the public of our consideration of JCAHO's request for approval of continued deeming authority for hospices. This notice also solicits public comment on the ability of JCAHO requirements to meet or exceed the Medicare conditions for participation for hospices.

II. Evaluation of Deeming Authority Request

On November 26, 2002, JCAHO submitted all the necessary materials to enable us to make a determination concerning its request for reapproval as a deeming organization for hospices. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of JCAHO will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of JCAHO standards for hospice care as compared with our comparable hospice conditions of participation as described in our regulations at § 418.1 through § 418.405.
- JCAHO's survey process to determine the following:
  - —The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  - —The comparability of JCAHO processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  - —JCAHO's processes and procedures for monitoring providers or suppliers found out of compliance with JCAHO program requirements. These monitoring procedures are used only when JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7 (d).
  - —JCAHO's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
  - —JCAHO's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.
  - —The adequacy of JCAHO's staff and other resources, and its financial viability.
  - —JCAHO's capacity to adequately fund required surveys.
  - —JCAHO's policies with respect to whether surveys are announced or unannounced.
  - —JCAHO's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

III. Response to Public Comments and Notice Upon Completion of Evaluation

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 comments we receive by the date and time specified in the **DATES** section of this preamble and will respond to the public comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1589 Filed 1–23–03; 8:45 am]

BILLING CODE 4121–PN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3113–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 12, 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (the Committee). The Committee provides advice and recommendations to us about clinical issues. Among other things, the Committee advises us on whether adequate evidence exists to determine whether specific medical items and services are reasonable and necessary under Medicare law. The Committee will discuss and make recommendations concerning the quality of the evidence and related issues for the use of a left ventricular assist device as ''destination'' (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Notice of this action is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The public meeting announced will be held on Wednesday, March 12, 2003 from 7:30 a.m. until 3:30 p.m., E.S.T.

Deadline for Presentations and Comments: Interested persons may present data, information, or views orally or in writing, on issues pending before the committee. Written presentations and comments must be submitted to the Executive Secretary by February 20, 2003, 5 p.m., E.S.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by February 26, 2003 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 338–339, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at *klong@cms.hhs.gov;* Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.cms.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at (410) 786–5702 or by e-mail at *klong@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (the Committee), which provides advice and recommendations to us about clinical issues. A revised charter was signed by the Secretary on November 22, 2002 (67 FR 79124). This notice announces the following public meeting of the Committee.

Meeting Topic

The Committee will discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of a left ventricular assist device as ''destination'' (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage.*

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section, and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Panel member before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2003.

Robert A. Streimer,

Acting Director, Office of Clinical Standards and, Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1588 Filed 1–23–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–5112]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOVOSEVEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOVOSEVEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

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

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product NOVOSEVEN (rhFVIIa). NOVOSEVEN is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NOVOSEVEN (U.S. Patent No. 4,784,950) from ZymoGenetics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 4, 2000, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of NOVOSEVEN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NOVOSEVEN is 3,954 days. Of this time, 2,904 days occurred during the testing phase of the regulatory review period, while 1,050 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: May 29, 1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 1988.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: May 10, 1996. FDA has verified the applicant's claim that the product license application (PLA) for NOVOSEVEN (PLA 96–0597) was initially submitted on May 10, 1996.

3. *The date the application was approved*: March 25, 1999. FDA has verified the applicant's claim that PLA 96–0597 was approved on March 25, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 25, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 23, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 19, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–1567 Filed 1–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Transmissible Spongiform Encephalopathies 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 February 20, 2003; 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1449, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 20, 2003, the committee will listen to updates on: Implementation of the variant Creutzfeldt-Jakob Disease (vCJD)

guidance (''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products''; this guidance can be accessed at http://www.fda.gov/cber/guidelines.htm) and its affect on blood supply, and an update on bovine spongiform encephalopathy epidemiology and food chain controls. The committee will then discuss consideration of labeling claims for transmissible spongiform encephalopathy (TSE) agent clearance in plasma derivatives.

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 February 13, 2003. Oral presentations from the public will be scheduled between approximately 10:10 a.m. to 10:30 a.m. and between approximately 3 p.m. to 3:40 p.m. on February 20, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 13, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 14, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–1566 Filed 1–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

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 should 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 the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Sample Survey of Registered Nurses 2004 (OMB No. 0915–0192)—Revision

The National Sample Survey of Registered Nurses (NSSRN) is carried out to assist in fulfilling two Congressional mandates. Section 792 of the Public Health Service Act (42 U.S.C. 295k), calls for the collection and analysis of data on health professions. Section 806 (f) of the Public Health Service Act (42 U.S.C. 296e) requires that discipline specific workforce information and analytical activities are carried out as part of the advanced nursing education, workforce diversity, and basic nursing education and practice programs.

Government agencies, legislative bodies and health professionals used data from previous national sample surveys of registered nurses to inform workforce policies. The information from this survey will continue to serve policy makers, and other consumers. Furthermore data collected in this survey will assist in determining the impact that changes in the health care system is having on employment status of registered nurses (RNs), the setting in which they are employed and the proportion of RNs who are employed full time and part time in nursing. The data will also indicate the number of RNs who are employed in jobs unrelated to nursing.

The proposed survey design for the 2004 NSSRN follows that of the previous seven surveys. A probability sample is selected from a sampling frame compiled from files provided by the State Boards of Nursing in the 50 States and the District of Columbia. These files constitute a multiple sampling frame of all RNs licensed in the 50 States and the District of Columbia. Sampling rates are set for each State based on considerations of statistical precision of the estimates and the costs involved in obtaining reliable national and State level estimates.

Each sampled nurse will be asked to complete a self-administered questionnaire, which includes items on educational background, duties, employment status and setting, geographic mobility, and income.

Estimated burden is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Questionnaires	39,360	1	39,360	.33	12,989

Send comments to Susan Queen, Ph.D., HRSA Reports Clearance Officer, Room 16C–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 17, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–1568 Filed 1–23–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supporting Networks of HIV Care; National Training and Technical Assistance Cooperative Agreements Announcement of Sole Source Awards

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Announcement of Sole Source Awards.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the funding of two sole source cooperative agreements of fiscal year (FY) 2002 Health and Human Services Minority AIDS Initiative (MAI) funds. The two organizations funded will implement the Supporting Networks of HIV Care, National Training and Technical Assistance Cooperative Agreements. These cooperative agreements are an essential part of the HRSA HIV/AIDS Bureau's (HRSA/HAB) response to the severe and ongoing HIV/AIDS crisis within racial and ethnic minority communities.

Recipients of these two awards are Communities Advocating for Emergency Assistance and Relief (CAEAR) Coalition Foundation in the amount of $2,200,000 and the National Minority AIDS Council (NMAC) in the amount of $600,000. Funds are awarded for a 1-year project period starting September 30, 2002, and ending September 29, 2003.

In partnership with HRSA/HAB, these two cooperative agreements will provide training, education, technical assistance, and related informational resources to non-profit, minority community- and faith-based organizations (C/FBOs) serving people of color living with and affected by HIV/AIDS. Select minority C/FBOs will receive assistance in response to their specific needs. The assistance will be designed to improve staff capabilities and organizational capacity for the provision of high quality, comprehensive HIV primary health care, and support services. C/FBOs that receive Ryan White Comprehensive AIDS Response Emergency (CARE) Act funds directly from HRSA/HAB for service delivery are not eligible for assistance. The long-term goal of these cooperative agreements is to increase and improve HIV primary care infrastructure in communities of color. A related goal is to equip organizations serving communities of color to become new members of the CARE Act community.

Assistance will be provided in the following areas: staff and board development and management, needs assessment, strategic planning, linkages and referrals, clinical and support service delivery and management, financial management, resource development, management information systems, quality management, program evaluation, and the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Services will be available through these cooperative agreements by early January 2003. The HRSA/HAB will have direct involvement in all planning, implementation, and evaluation related activities to ensure timely execution of work plans and quality in the delivery of services and the development of materials.

Background: The CAEAR Coalition Foundation and NMAC were found uniquely qualified to administer this cooperative agreement given their organizational characteristics, strengths and experience working directly with HRSA/HAB. Both organizations have significant experience developing successful activities and programs to support HIV/AIDS service providers nationally.

The CAEAR Coalition Foundation was formed by communities affected by the HIV/AIDS epidemic during the initial authorization of the Ryan White CARE Act. For a little over a decade, CAEAR Coalition Foundation has been a leading voice in HIV/AIDS service delivery and planning. The CAEAR Coalition Foundation represents over 250 governmental and CBOs, including Titles I and III grantees, and the communities they serve. Their membership is significant given its inclusion of organizations serving large metropolitan areas (500,000+ residents) most severely impacted by HIV/AIDS. It also includes CBOs in rural, underserved, and racial/ethnic minority communities facing existing and emerging HIV epidemics. The CAEAR Coalition Foundation's close relationship with relevant CARE Act grantees and other organizations nationally will allow for extensive outreach and identification of organizations in most need of this type of assistance. The CAEAR Coalition Foundation conducts a variety of research projects and educational activities to increase provider and patient knowledge about care, treatment, and support services and strategies to fight the HIV epidemic. The CAEAR Coalition Foundation works to stay abreast of the current needs of providers and address those needs. There is no other national AIDS organization with CAEAR Coalition Foundation membership and CARE Act expertise. CAEAR Coalition Foundation has experience managing HRSA funds and related initiatives.

Since 1987, NMAC has worked to develop leadership and capacity within communities of color to address HIV infection. NMAC is the only national organization founded specifically to support minority CBOs to foster new leadership and address the unique challenges HIV/AIDS presents for racial/ethnic minorities. Over 3,000 minority CBOs have joined. NMAC is the only national minority AIDS organization providing on-line training, technical assistance, and ''chat room'' opportunities for minority CBOs. NMAC's Web site receives approximately 36,000 hits per day. NMAC's LifeLine provides e-mail announcements to over 8,000 governmental and non-governmental organizations and individuals regarding the availability of grants for HIV service delivery, opportunities for training and TA, national conferences, and other important updates. NMAC has experience managing MAI funds and implementing related activities in the areas of HIV/AIDS treatment, fiscal management, board development, effective utilization of technology, and community planning.

FOR FURTHER INFORMATION CONTACT: Additional information may be obtained from Ms. Rene Sterling, HIV/AIDS Bureau, 5600 Fishers Lane, Room 7–47, Rockville, MD 20857; telephone (301) 443–7778, fax (301) 594–2835, e-mail *RSterling@hrsa.gov.*

Paperwork Reduction Act

If there is a data collection associated with this application OMB approval will be sought.

Dated: January 15, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–1569 Filed 1–23–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, In Vivo Cellular and Molecular Imaging Centers (ICMICs).

Date: March 10–11, 2003.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Administrator, Division of Extramural Affairs, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892, (301) 496–7576, *bielatk@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1562 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group, Comparative Medicine Review Committee.

Date: February 4–5, 2003.

Open: February 4, 2003, 8 a.m. to 8:30 a.m.

Agenda: To discuss program planning and other issues.

Place: Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

Closed: February 4, 2003, 8:30 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott, Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

Contact Person: Camille M. King, Ph.D., Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Rockledge Centre, MSC 7965, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892–7965, (301) 435–0815, *kingc@ncrr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Center for Research Resources Initial Review Group, Clinical Research Review Committee.

Date: February 12–13, 2003.

Open: February 12, 2003, 8 a.m. to 9 a.m.

Agenda: To discuss program planning and other issues.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Closed: February 12, 2003, 9 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sheryl K. Brining, Ph.D., Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Rockledge Centre, MSC 7965, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892–7965, (301) 435–0809, *brinings@ncrr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1547 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Biomedical Research Technology.

Date: February 10–11, 2003.

Time: February 10, 2003, 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Mohan Viswanathan, PhD, Scientific Review Administrator, National Center for Research Resources, National Institutes of Health, Office of Review, 6705 Rockledge Drive, MSC 7965, One Rockledge Centre, Room 6018, Bethesda, MD 20892, (301) 435–0829, *viswanathanm@ncrr.nih.gov*.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Biomedical Research Technology.

Date: February 12, 2003.

Time: 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Center for Research

Resources, National Institutes of Health, 6705 Rockledge Drive, MSC 7965, One Rockledge Centre, Room 6018, Bethesda, MD 20892, (301) 435–0814, *lambertc@ncrr.nih.gov*.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Science Education Partnership Award.

Date: February 25–27, 2003.

Time: February 25, 2003, 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Bethesda Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: D. G. Patel, BPHA, MSC, MA, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, (301) 435–0811.

(Catalogue of Federal Domestic Assistance Program Nos. 93.305, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1548 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel. NHLBI, Mentored Scientist Development Award.

Date: March 6–7, 2003.

Time: 7:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Roy L White, PhD., Scientific Review Administrator, Review Branch, Room 7192, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892, 301–435–0287.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1555 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel.

Date: February 25, 2003.

Time: 9 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Irina Gordienko, Scientific Review Administrator, Division of Extramural Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, MSC 7924, Bethesda, MD 20892, 301–435–0270.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1556 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Structure and Function of Vascular Integrins.

Date: February 24, 2003.

Time: 6:30 p.m. to 10:30 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Irina Gordienko, Scientific Review Administrator, Division of Extramural Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, MSC 7924, Bethesda, MD 20892, (301) 435–0270.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1557 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Acute Lung Injury SCCOR RFA–HL–02–014.

Date: February 27–28, 2003.

Time: 8 a.m to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Chitra Krishnamurti, PhD, Scientific Review Administrator, Review Branch, Room 7206, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1558 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, COPD Clinical Research Network—Data Coordinating Center.

Date: March 6–7, 2003.

Time: 8 a.m. to 5 p.m..

Agenda: To review and evaluate grant applications.

Place: Sheraton Columbia Hotel, 10207 Wincopin Circle, Ellicott Conference Room, Columbia, MD 21044.

Contact Person: Patricia A. Haggerty, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892, (301) 435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1559 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant application and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Vascular Cell Function and Atherosclerosis.

Date: February 25, 2003.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: William J. Johnson, Scientific Review Administrator, NHLBI Review Branch, Division of Extramural Affairs, Two Rockledge Centre, Room 7184, MSC7924, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–0275.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1560 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Lipid and Lipoprotein Metabolism in Atherosclerosis.

Date: February 25, 2003.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: William J. Johnson, Scientific Review Administrator, NHLBI Review Branch, Division of Extramural Affairs, Two Rockledge Centre, Room 7184, MSC7924, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–0275.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1561 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Food & Waterborne Diseases Integrated Research Network: Coordinating & Biostatistics Center.

Date: February 5, 2003.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: 6700 B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Eleazar Cohen, Ph.D., Scientific Review Administrator, NIAID/DEA, Scientific Review Program, Room 2217, 6700B Rockledge Drive, MSC–7616, Rockville, MD 20892 (301) 496–2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1549 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee.

Date: February 12–14, 2003.

Time: February 12, 2003, 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Time: February 13, 2003, 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Time: February 14, 2003, 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2149, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–3528, *gm12w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 15, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1550 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institutes of Allergy and Infectious Diseases Special Emphasis Panel, Respiratory Pathogens Reference Laboratory Support.

Date: February 7, 2003.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: 6700–B Rockledge Drive, NIH/NIAID, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Paula S. Strickland, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2217, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1551 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. Autoimmunity Centers of Excellence.

Date: February 5–7, 2003.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Cheryl K. Lapham, PhD, Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700–B Rockledge Drive, MSC 7616, Room 2156, Bethesda, MD 20892–7616, 301–496–2550, *clapham@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1552 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. Specialized Centers of Research.

Date: March 3, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Aftab A. Ansari, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1553 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. Comprehensive International Program of Research on AIDS (CIPRA), UO1, Exploratory/Developmental Grant Program.

Date: January 24, 2003.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700–B Rockledge Drive, 5200, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter R. Jackson, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2154, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 496–2550, *pjackson@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. Comprehensive International Program of Research on AIDS (CIPRA), RO3, Planning and Organization Grant.

Date: January 24, 2003.

Time: 12:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700–B Rockledge Drive, 5200, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter R. Jackson, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2154, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 496–2550, *pjackson@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1554 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special

Emphasis Panel, Review of Program Project Applications (PO1s).

Date: February 21, 2003.

Time: 9:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS, Rall Building, Conference Room 101–A, Research Triangle Park, NC 27709.

Contact Person: Linda K Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Review of R01 Grant Applications.

Date: March 3, 2003.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS, Building 4401, East Campus, 122, Research Triangle Park, NC 27707, (Telephone Conference Call).

Contact Person: Linda K Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1563 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDCD.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Deafness and Other Communication disorders, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDCD.

Date: March 28, 2003.

Open: 7:45 a.m. to 8:15 a.m.

Agenda: Reports from Institute Staff.

Place: National Institutes of Health, 5 Research Court, Rockville, MD 20850.

Closed: 8:15 a.m. to 5:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 5 Research Court, Rockville, MD 20850.

Contact Person: Robert J. Wenthold, PhD, Director, Division of Intramural Research, National Institute on Deafness and Other Communication Disorders, 5 Research Court, Room 2B28, Rockville, MD 20852, 301–402–2829.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: January 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–1564 Filed 1–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4809–N–04]

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.

EFFECTIVE DATE: January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (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 the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration.* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 16, 2003.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 03–1413 Filed 1–23–03; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Drilling of Additional Exploration and Development Natural Gas Wells in and Adjacent to the Muddy Ridge and Pavilion Fields and the Surrounding Areas, Wind River Indian Reservation, Fremont County, WY

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), in cooperation with the Shoshone and Arapahoe Tribes and the Bureau of Land Management (BLM), intends to gather information necessary for preparing an Environmental Impact Statement (EIS) for the drilling of additional exploration and development natural gas wells in and adjacent to the Muddy Ridge and Pavilion fields and the surrounding areas, Wind River Indian Reservation, Fremont County, Wyoming. The

purpose of the proposed action is to meet the Tribes' need to maximize their economic benefit from this trust resource. A description of the proposed project, location, and environmental consideration to be addressed in the EIS are provided in the **SUPPLEMENTARY INFORMATION** section.

DATES: Written comments on the scope and content of the EIS must arrive by February 25, 2003.

ADDRESSES: You may mail or hand carry written comments to Ray A. Nation, Environmental Coordinator, Bureau of Indian Affairs, Wind River Agency, P.O. Box 158, Fort Washakie, Wyoming 82514.

FOR FURTHER INFORMATION CONTACT: Ray A. Nation, (307) 332–3718, or Stuart Cerovski, (307) 332–8426.

SUPPLEMENTARY INFORMATION: The Wind River Natural Gas Development Project area is generally located in Townships 3 and 4 North, Range 2 through 5 East, in Fremont County, Wyoming. The project area contains about 92,000 acres.

The Wind River Project consists of the drilling of up to 325 new wells in the project area over the next 20 years. Economic conditions and the evaluation of the drilling results would determine the actual number of wells that would be drilled. In addition, the project will require the construction of 325 associated lease roads (excluding 153 existing wells), 78 miles of new natural gas pipeline (excluding 62 existing miles), and 18,175 horsepower of new compression on approximately six new sites on private, federal and tribal lands. This 18,175 horsepower will increase the current 14,540 horsepower natural gas compression capacity total to 32,715 horsepower.

During the drilling and construction phase, the proposed well pads, pipelines and roads would result in the short-term disturbance of approximately 1,863 acres, or 2.02 percent of the total surface area in the project area. Well pads would be reduced in size following the completion of drilling operations, and pipeline right-of-ways restored upon completion of construction. Long-term disturbance would affect approximately 922 acres or 1.00 percent of the total surface area.

The Wind River Project area currently contains two active natural gas fields that are predominantly developed under 40 and 20-acre spacing, depending upon formation. An existing road network developed to service existing drilling and production activities access the Wind River Project area, but it is expected that the drilling of additional wells within the project area would require the construction of additional roads. Existing pipelines and new pipelines, including new gathering lines, looplines and tie-ins to existing interstate pipelines, would transport the produced gas within the project area.

While the Wind River environmental analysis is being conducted, the BIA/BLM will allow some drilling of wells within the proposed project area. Interior drilling will be monitored by the BIA/BLM to ensure that activities do not adversely affect the environment or prejudice the completion of the environmental analysis.

Public Comment Availability

Public meetings on the scope and content of the EIS were held on October 22, 2002, in Pavilion, Wyoming, and October 23, 2002, in Fort Washakie, Wyoming. Comments from these meetings, plus all others we receive, including names and addresses of respondents, will be available for public review at the mailing address shown in the **ADDRESSES** section, during regular business hours, 8 a.m. to 5 p.m., Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish us to withhold your name and/or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. We will not, however, consider anonymous comments. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses will be made available for public inspection in their entirety.

Authority

This notice is published in accordance with section 1503.1 of the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508) implementing the procedural requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and the Department of the Interior Manual (516 DM 1–6), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.1.

Dated: January 10, 2003.

Aurene M. Martin,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 03–1592 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–962–1410–HY–P; F–14940–P, F–14940–R, F–14940–S, F–14940–C2, DYA–9]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, DOI.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: As required by 43 CFR 2650.7(d), notice is hereby given that an appealable decision approving lands for conveyance pursuant to the Alaska Native Claims Settlement Act will be issued to Dinyea Corporation for lands in Tps. 14 and 15 N., R. 8 W., and T. 14 N., R. 9 W., Fairbanks Meridian, Alaska, located in the vicinity of Stevens Village, Alaska, aggregating 21,488.29 acres. Notice of the decision will also be published four times in the *Fairbanks Daily News-Miner*.

DATES: The time limits for filing an appeal are:

1. Any party claiming a property interest which is adversely affected by the decision shall have until February 24, 2003 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

ADDRESSES: A copy of the decision may be obtained from: Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Jerri Sansone, (907) 271–3231.

Jerri Sansone,

Land Law Examiner, Branch of ANCSA Adjudication.

[FR Doc. 03–1540 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–130–1020–PG; GP3–0061]

Call for Nominations for the Eastern Washington Resource Advisory Council

AGENCY: Bureau of Land Management (BLM).

ACTION: Notice of Resource Advisory Council call for nominations.

SUMMARY: The purpose of this notice is to solicit public nominations for the Bureau of Land Management (BLM) Eastern Washington Resource Advisory Council (RAC) that has an open position to represent environmental/conservation interests. This position will expire in 2006. The RAC provides advice and recommendations to the BLM and the USDA Forest Service on land use planning and management of public lands within their geographic areas. Public nominations will be considered for 60 days after the publication date of this notice.

The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by BLM.

Section 309 of FLPMA directs the Secretary to select 10- to 15-member citizen-based advisory councils that are established and authorized consistent with requirements of the Federal Advisory Committee Act (FACA). As required by the FACA, RAC membership must be balanced and representative of the various interests concerned with management of public lands.

Individuals may nominate themselves or others. Nominees for the Eastern Washington RAC must be residents of Washington. Nominees will be evaluated based on their education, training, experience, and their knowledge of the geographical area of the RAC. Nominees should have demonstrated a commitment to collaborative resource decision-making. All nominations submitted must include letters of reference from represented interests or organizations, a completed background information nomination form, as well as any other information that speaks to the nominee's qualifications.

DATES: All nominations should be received in the Oregon BLM State Office by March 24, 2003.

FOR FURTHER INFORMATION CONTACT: Pam Robbins: (503) 808–6306, *pam_robbins@blm.gov*, BLM State Office, 333 Southwest 1st Avenue, Portland, Oregon 97204.

Dated: January 17, 2003.

Joseph K. Buesing,

District Manager.

[FR Doc. 03–1594 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–310–0777–XG]

Notice of Resource Advisory Council Vacancy

AGENCY: Bureau of Land Management; Northeast California Resource Advisory Council; Susanville, California.

ACTION: Notice of vacancy and call for nominations.

SUMMARY: Pursuant to authorities in the Federal Advisory Committees Act (Pub. L. 92–463) and the Federal Land Policy and Management Act (Pub. L. 94–579), the U. S. Bureau of Land Management is seeking nominations to fill a vacant seat on the Northeast California Resource Advisory Council. The person selected to fill the vacancy will complete an unexpired term that ends in September 2004. The appointee will be eligible to compete for the full three-year term when the current term expires.

SUPPLEMENTARY INFORMATION: The council vacancy is in membership category three: persons representing issues and concerns of Native American Tribes. The appointment will be made by the Secretary of the Interior, as are all BLM Resource Advisory Council appointments. The person selected must have knowledge or experience in the interest area specified, and must have knowledge of the geographic area under the council's purview (the northeast portion of California and the northwest corner of Nevada).

Qualified applicants must have demonstrated a commitment to collaborate with varied interests to solve a broad spectrum of natural resource issues.

Nomination forms are available by contacting BLM Public Affairs Officer Joseph J. Fontana, 2950 Riverside Drive, Susanville, CA 96130; by telephone (530) 252–5332; or e-mail, *jfontana@ca.blm.gov*. Nominations must be returned to: Bureau of Land Management, 2950 Riverside Drive, Susanville, CA 96130, Attention Public Affairs Officer by February 24, 2003. Individuals can nominate themselves, or interest groups can submit nominations. Nominations must include letters of support from the interest groups the nominee will represent.

FOR ADDITIONAL INFORMATION: Contact BLM Alturas Field Manager Tim Burke at (530) 233–4666, or Public Affairs Officer Joseph J. Fontana at the above phone or e-mail address.

Joseph J. Fontana,

Public Affairs Officer.

[FR Doc. 03–1660 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–6333–JE; HAG03–0004]

Notice of Intent To Prepare an Environmental Impact Statement for Restoration and Timber Salvage Within the Timbered Rock Fire, Medford District, OR

AGENCY: Bureau of Land Management, U.S. Department of the Interior.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS) and conduct public scoping for restoration and timber salvage within the Timbered Rock Fire, Medford District, Oregon.

SUMMARY: This document provides notice that the Bureau of Land Management (BLM) intends to prepare an EIS for the restoration and timber salvage within the Timbered Rock Fire, Medford District, Oregon. This planning activity encompasses 11,755 acres of BLM-administered land that was burned in the summer of 2002 Timbered Rock Wildfire, which burned in total 26,974 acres. This EIS will fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), and BLM management policies. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, and national needs and concerns. The public scoping process will help identify issues to be addressed, possible alternatives, data gaps, and possible conflicts with existing management direction. The purpose of the EIS is to take a more detailed look at restoration activities, salvage logging opportunities, and opportunities for long-term resource studies.

DATES: This notice initiates the public scoping process. Comments on issues and the scope of the analysis can be submitted in writing to the address listed below and will be accepted throughout the creation of the EIS. All public meetings will be announced through the local news media, newsletters, and the Washington/Oregon BLM Web site (*http://www.or.blm.gov*) at least 15 days prior

to the event. The minutes and list of attendees for each meeting will be available to the public and open for 30 days following the publication of this notice to any participant who wishes to clarify the views they expressed. Early participation is encouraged and will help determine the future management of the public lands burned by the Timbered Rock Fire.

ADDRESSES: Written comments should be sent to the Bureau of Land Management, ATTN: Jean Williams, 3040 Biddle Road, Medford, OR 97504. Comments, including names and street addresses of respondents, will be available for public review at the Medford District office during regular business hours (7:45 AM to 4:30 PM) Monday through Friday, except holidays, and may be published as part of the environmental analysis or other related documents. Individual respondents may request confidentiality. If you wish to withhold your name or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT: For further information, and/or to have your name added to our mailing list, contact Jean Williams at (541) 618–2385 or John Bergin at (541) 618–2265.

SUPPLEMENTARY INFORMATION: Restoration of lands and economic recovery of resources damaged by wildfire are important activities following control of wildfires. The level and intensity of these activities can vary greatly depending upon a variety of factors. Public lands administered by the BLM in the Timbered Rock Fire are located entirely within a Late-Successional Reserve (LSR) and Tier 1 Key watershed and contains 18 owl activity centers. These land use allocations will have an effect on restoration actions and salvage opportunities that will be addressed in the Environmental Impact Statement. The environmental analyses will, as appropriate, address a range of restorative options, salvage opportunities, and potential long-term study opportunities. A No Action Alternative will be analyzed. One or more of the alternatives may address some modification to Standards and Guidelines from the Northwest Forest Plan (NFP), the Medford District Resource Management Plan (RMP), and site-specific LSR Assessments (LSRA) that apply to the fire. Input from the scoping process will be used to determine the scope of the analysis consistent with the requirements of 40 CFR 1501.7 and 1508.22. The scoping process includes:

- Defining the scope of the analysis and the nature of the decisions to be made.
- Identify the issues for consideration within the environmental analyses;
- Identify possible alternatives;
- Identify possible or potential environmental effects;
- Identify groups or individuals that would be interested in or affected by the restorative or economic recovery actions.

The BLM will seek information, comments, and assistance from Federal, State, and local agencies and other individuals, organizations, or businesses interested in or affected by the actions. Disciplines that may be included on the analysis team include forestry, soils, hydrology, fisheries, wildlife, fuels management, and others.

Possible cooperating agencies include the U.S. Fish and Wildlife Service, the National Marine Fisheries Service, the Army Corps of Engineers, and the Rogue River National Forest. The public is asked to identify issues they believe should be assessed in the Environmental Impact Statement and provide ideas and suggestions on restorative actions and economic recovery of timber resources and alternatives they think should be considered.

Dated: December 4, 2002.

Kathy Eaton,

Acting Oregon/Washington State Director.

[FR Doc. 03–1539 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–010–1232–HB–UT17–24–1A]

Notice of Final Supplementary Rules on Public Lands in Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Final supplementary rules for certain public lands managed by the Bureau of Land Management within the Little Sahara Special Recreation Management Area, Fillmore Field Office, Utah.

SUMMARY: The Bureau of Land Management (BLM) is issuing final supplementary rules to apply to the public lands within the Little Sahara Special Recreation Management Area, Fillmore Field Office, Utah. The rules are necessary for the management of actions, activities, and public use on certain public lands which may have or are having adverse impacts on persons using public lands, on property, and on resources located on public lands located in, or acquired for inclusion within, the Little Sahara Special Recreation Management Area.

EFFECTIVE DATE: February 24, 2003.

ADDRESSES: Mail: Bureau of Land Management, 35 E 500 N, Fillmore, Utah 84631. Personal or messenger delivery: 35 E 500 N, Fillmore, Utah 84631.

FOR FURTHER INFORMATION CONTACT: Ferris Clegg, Bureau of Land Management, Richfield Field Office, 150 East 900 North, Richfield, Utah 84701. Telephone (435)896–1500.

SUPPLEMENTARY INFORMATION:

I. Publication of Proposed Supplementary Rules and Discussion of Comments

The proposed supplementary rules for the Little Sahara Special Recreation Management Area were published in the **Federal Register** on August 22, 2002 (67 FR 54456), and allowed 30 days for public comment.

We received no comments on the proposed supplementary rules. Therefore, we are publishing them as final supplementary rules without change, except for the following:

(1) We are correcting typographical or printing errors that appeared in the proposed supplementary rules;

(2) We are editorially changing the heading of Sec. 3.0 from ''Permits and Fees'' to ''Fees and Contracts,'' which better reflects the contents of the following two sections; and

(3) We are adding to Sec. 1.2 the requirement that drivers must have either a valid motor vehicle operator's license or a safety certificate issued by the Utah Division of Parks and Recreation. We also removed the erroneous requirement in this section of the proposed supplementary rules that a child must be 8 years old or older to ride as a passenger on an OHV. These are not policy changes, but rather amendments to conform with Utah State law and rules (The Utah Off-Highway Vehicle Act, and The Utah Board of Parks and Recreation Rules, 41–22–30. Supervision, Safety Certificate, or Driver License Required—Penalty).

II. Discussion of the Supplementary Rules

The Utah State Director of the Bureau of Land Management is establishing these supplementary rules under 43 CFR 8365.1–6. They are necessary for the protection of persons, property and public lands and resources within—

- The Little Sahara Special Recreation Management Area,
- Lands acquired for inclusion in the Little Sahara Special Recreation Management Area, and
- All lands that may be incorporated into the Little Sahara Special Recreation Management Area.

These rules are in addition to and supplement the regulations found in 43 CFR part 8300.

The affected lands are located in the following areas:

Salt Lake Base Meridian

T.12S., R.4W.
Sec. 19, lots 3 and 4, E½SW¼, and SE¼;
Sec. 20, W½SW¼, and SE¼SW¼;
Sec. 28, S½SW¼;
Sec. 29, W½NE¼, SE¼NE¼, W½, and SE¼;
Secs. 30 to 33, inclusive;
Sec. 34, SW¼NW¼, SW¼, and S½SE¼.
T.13S., R.4W.
Secs. 3 to 10, inclusive;
Sec. 15, N½, SW¼, N½SE¼, and SW¼SE¼;
Secs. 16 to 21, inclusive;
Sec. 22, NW¼, W½SW¼;
Sec. 28, lots 1, 2, 3, and 4;
Sec. 29, lots 1, 2, 3, and 4, SW¼NE¼, S½NW¼, SW, and W½SE¼;
Sec. 30 and 31;
Sec 32, W½E½, W½.
T.14S., R4W.
Sec. 5, lots 1, 2, 3, and 4, S½N½, SW¼, and W½SE¼;
Secs. 6 and 7;
Sec. 8, W½;
Sec. 17, W½NW¼;
Sec. 18, T.12S., R5W.;
Sec. 24, S½;
Sec. 25 to 29, inclusive;
Sec .30, SE¼NE¼, SE¼SW¼, and SE¼;
Secs. 31 to 36, inclusive.
T.13S., R5W.
Secs. 1 to 36, inclusive.
T.14S., R5W.
Secs. 1 to 5, inclusive;
Sec. 6, lots 1 to 9, inclusive, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 7, E½;
Secs. 8 to 15, inclusive;
Sec. 16, N½;
Sec. 17, N½;
Sec. 18, NE¼NE¼;
Secs. 22 to 24, inclusive.

III. Procedural Requirements

Executive Order 12866, Regulatory Planning and Review

These supplementary rules are not a significant regulatory action and are not subject to review by Office of Management and Budget under Executive Order 12866. These supplementary rules will not have an effect of $100 million or more on the economy. They are directed at preventing unlawful personal behavior on public lands, for purposes of protecting public health and safety. They 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. These proposed supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The supplementary rules do not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; nor do they raise novel legal or policy issues. The supplementary rules merely enable BLM law enforcement personnel to enforce state laws where appropriate on public lands.

National Environmental Policy Act

BLM has prepared an environmental assessment (EA) and has found that the supplementary rules do not constitute a major Federal action significantly affecting the quality of the human environment under section 102(2)(C) of the Environmental Protection Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). The supplementary rules will enable BLM law enforcement personnel to cite persons not obeying the rules of the Little Sahara Special Recreation Area for the purpose of protecting public health and safety. BLM has placed the EA and the Finding of No Significant Impact (FONSI) on file in the BLM Administrative Record at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980, as amended, 5 U.S.C. 601–612, (RFA) to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule will have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. The supplementary rules do not pertain specifically to commercial or governmental entities of any size, but contain rules to protect the health and safety of individuals, property, and resources on the public lands. Therefore, BLM has determined under the RFA that these supplementary rules will not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

These supplementary rules do not constitute a ''major rule'' as defined in SBREFA (5 U.S.C. 804(2)). Again, the supplementary rules pertain only to individuals who may use the public lands. In this respect, the regulation of such use is necessary to protect the public lands and facilities and those, including small business concessioners and outfitters, who use them. The supplementary rules have no effect on business-commercial or industrial use of the public lands.

Unfunded Mandates Reform Act

These supplementary rules do not impose an unfunded mandate on state, local, or tribal governments or the private sector of more than $100 million per year; nor do these supplementary rules have a significant or unique effect on state, local, or tribal governments or the private sector. The supplementary rules do not require anything of state, local, or tribal governments. Therefore, BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*)

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

The supplementary rules do not represent a governmental action capable of interfering with constitutionally protected property rights. The supplementary rules do not address property rights in any form, and do not cause the impairment of anyone's property rights. Therefore, the Department of the Interior has determined that the supplementary rules will not cause a taking of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13132, Federalism

The supplementary rules will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The supplementary rules apply in only one state, Utah, and do not address jurisdictional issues involving the state government. Therefore, in accordance with Executive Order 13132, BLM has determined that these supplementary rules do not have sufficient Federalism

implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, Utah State Office of BLM has determined that these supplementary rules will not unduly burden the judicial system and that they meet the requirements of sections 3(a) and 3(b)(2) of the Order.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with E.O. 13175, we have found that this final rule would not include policies that have tribal implications. The rule would not affect lands held for the benefit of Indians, Aleuts, and Eskimos. The rule would apply only to persons driving OHVs on certain public lands in Utah.

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a significant energy action. It will not have an adverse effect on energy supplies. It will have no discernible effect on the production or sale of energy minerals, and any effect on the consumption of such minerals, either in manufacturing OHV equipment or traveling to OHV areas, will be imperceptible, since the provision should not have a measurable effect on either activity.

Paperwork Reduction Act

These supplementary rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Author

The principal author of these supplementary rules is Ferris Clegg of the Fillmore Field Office, assisted by Ted Hudson of the Regulatory Affairs Group, Washington Office, BLM.

Dated: October 17, 2002.

Sally Wisely,

State Director.

Supplementary Rules, Little Sahara Special Recreation Management Area

Sec. 1.0 Vehicle Equipment Requirements

Sec. 1.1 Safety Flags

a. A safety flag is required on all off-highway vehicles. This includes all all-terrain vehicles (ATVs), dirt bikes and dune buggies. You must not operate, or give any person permission to operate, an off-highway vehicle that is not equipped with a safety flag within the Little Sahara Special Recreation Management Area.

b. The safety flag must be—

1. Red or orange in color and a minimum of six by 12 inches;

2. Attached to the off-highway vehicle in such a manner that the top of the flag is at least eight feet above the surface of level ground.

Sec. 1.2 Minimum Age

a. You must be 8 years of age or older, and you must carry on your person either a valid motor vehicle operator's license or the appropriate safety certificate issued by the Utah Division of Parks and Recreation, to operate an off-highway vehicle within the Little Sahara Special Recreation Management Area.

b. You must not give any child under 8 years of age permission to operate any off-highway vehicle within the Little Sahara Special Recreation Management Area.

Sec. 1.3 Protective Headgear

a. You must not operate or ride on an off-highway vehicle within the Little Sahara Special Recreation Management Area unless you are wearing properly fitted, safety-rated protective headgear designed for motorized vehicle use, if you are under the age of 18.

b. You must not give permission to any person under the age of 18 to operate or ride on an off-highway vehicle within the Little Sahara Special Recreation Management Area unless that person is wearing properly fitted, safety-rated protective headgear designed for motorized vehicle use.

Sec. 2.0 Prohibited Acts

Sec. 2.1 Government Property

You must not vandalize, climb on or otherwise interfere or tamper with any building, structure, sign, water line, water tank, equipment, or any other government property or government contracted property within the Little Sahara Special Recreation Management Area.

Sec. 2.2 Spray Paint

The following are prohibited:

a. The use of spray paint or paint-ball guns within the Little Sahara Special Recreation Management Area except for:

1. The official business of any Federal, state, county, or local governmental entity, or

2. The necessary performance of work related to the maintenance or construction of any authorized improvements or facilities on public lands;

b. The possession of spray paint containers within the Little Sahara Special Management Area, except when such containers of spray paint are located—

1. In the trunk of a motor vehicle; or

2. In some other portion of the motor vehicle designed for the storage of luggage and not normally occupied by or readily accessible to the operator or passengers, if the motor vehicle is not equipped with a trunk.

Sec. 2.3 Glass Containers

Within the Little Sahara Special Recreation Management Area, you must not possess glass containers outside of vehicles, camp trailers, or tents.

Sec. 2.4 Bonfires

You must not knowingly create or maintain any large bonfire within the area of Little Sahara Special Recreation Management Area. For the purpose of this supplemental rule, a large bonfire means a fire with flames over three feet tall or a fire that cannot be contained in a 3-foot diameter area.

Sec. 2.5 Wooden Pallets

You must not bring into the Little Sahara Special Recreation Management Area or possess within the Little Sahara Special Recreation Management Area any pallets or lumber or wood products with nails or other metal objects affixed to such wood, lumber or wood products. You may carry or possess wood or lumber so long as they do not have nails or other metal objects attached to them.

Sec. 3.0 Fees and Contracts

Sec. 3.1 Fees

Except as provided in Sec. 3.2 of these supplementary rules—

a. You must not enter the Little Sahara Special Recreation Management Area by any means or ways, public or private, without properly paying required fees.

b. You must not enter, camp, park, or stay longer than one hour within the Little Sahara Special Recreation Management Area without properly paying required fees.

Sec. 3.2 Contracts

a. You may not enter the Little Sahara Special Recreation Management Area without paying required fees, unless you have a current, valid, annual pass contract or obtain a temporary contract in lieu of fees from BLM and sign it in the presence of the issuing officer.

b. You must not violate the terms, conditions, and stipulations of your current annual pass contract or a temporary contract in lieu of fees under paragraph a. of this section.

Sec. 4.0 Penalties

Under the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1733(a)), if you knowingly and willfully violate or fail to comply with any of the supplementary rules provided in this notice, you may be subject to a fine under 18 U.S.C. 3571 or other penalties in accordance with 43 U.S.C. 1733.

[FR Doc. 03–1541 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–1050–ET; WYW 155144]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 1,360 acres of public land for a period of 20 years to protect important paleontological resources within the Red Gulch Dinosaur Tracksite. This notice segregates the land for up to 2 years from surface entry and mining. The land will remain open to mineral leasing.

EFFECTIVE DATE: Comments and requests for a public meeting must be received on or before April 24, 2003.

ADDRESSES: Comments and meeting requests should be sent to the Wyoming State Director, Bureau of Land Management, P.O. Box 1828, Cheyenne, Wyoming 82003–1828.

FOR FURTHER INFORMATION CONTACT: Janet Booth, BLM Wyoming State Office, 307–775–6124.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management has filed an application to withdraw the following described public land from settlement, sale, location, or entry under the general land laws, including the mining laws, but not the mineral leasing laws, subject to valid existing rights:

Sixth Principal Meridian

T. 52 N., R. 91 W.,
Sec. 17, S½NE¼ and SE¼;
Sec. 20, N½, SE¼, and NE¼SW¼;
Sec. 21, NE¼, W½, N½SE¼, and SW¼SE¼.

The area described contains 1,360 acres in Big Horn County.

The purpose of the proposed withdrawal is to protect important paleontological resources of the Bureau of Land Management's Red Gulch Dinosaur Tracksite located near Shell, Wyoming.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Wyoming State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal should submit a written request to the Wyoming State Director within 90 days from the date of publication of this notice. If the authorized officer determines that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

This application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the land described above will be segregated as specified above unless the application is denied or cancelled or the withdrawal is approved prior to that date. Licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature which would not impact or impair the existing values of the area may be allowed with the approval of an authorized officer of the Bureau of Land Management during the segregative period.

Dated: January 14, 2003.

Alan L. Kesterke,

Associate State Director.

[FR Doc. 03–1542 Filed 1–23–03; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–462]

In the Matter of Certain Plastic Molding Machines with Control Systems Having Programmable Operator Interfaces Incorporating General Purpose Computers, and Components Thereof II; Notice of Commission Decision To Reverse an ALJ Determination on Statutory Authority and To Vacate ALJ Order No. 29; Termination of the Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to reverse an ALJ determination that subsection 337(g)(2) of the Tariff Act of 1930, as amended, 19 U.S.C. 1337(g)(2), contains the authority to issue a general exclusion order in an investigation in which all respondents appeared and have been terminated on the basis of settlement agreements. The Commission has also determined to vacate ALJ Order No. 29, denying a motion for summary determination of violation. Finally, the Commission has determined to terminate this investigation without reaching the issue of violation. The Commission will issue its Opinion shortly.

FOR FURTHER INFORMATION CONTACT: Jean Jackson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3104. Copies of the ALJ's order 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. 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*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the above-referenced investigation on August 23, 2001, based on a complaint filed by Milacron, Inc. (Milacron) of Cincinnati, OH, against 11 respondents. 66 FR 44374 (2001). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337) in the importation into the United States, sale for importation, and sale within the United States after importation of certain plastic molding machines with control systems having programmable operator interfaces incorporating general purpose computers, and components thereof, by reason of infringement of claims 1–4 and 9–13 of U.S. Patent No. 5,062,052. All named respondents have been terminated from the investigation on the basis of settlement agreements.

On April 18, 2002, Milacron filed a motion to amend the procedural schedule so that it would have an opportunity to file a motion for summary determination of violation of section 337 and to request a general exclusion order. On April 24, 2002, the ALJ issued Order No. 27, granting Milacron's request to amend the procedural schedule in the investigation to allow Milacron the opportunity to file a motion for summary determination of violation and to seek a general exclusion order under Commission rule 210.16 (c)(2). On May 17, 2002, complainant filed its motion for summary determination and request for a recommendation supporting a general exclusion order.

On June 11, 2002, the ALJ issued Order No. 29 denying Milacron's motion for summary determination of violation. On June 18, 2002, the ALJ issued a one-

paragraph ID (Order No. 30) terminating the investigation. On June 24 and June 25, 2002, respectively, Milacron and the IA petitioned for review of the ID and appealed Order No. 29.

The Commission determined to review and reverse the ALJ's ID terminating the investigation. 67 FR 47569 (July 19, 2002). The Commission also determined to review the ALJ's determination in Order No. 29 that the Commission has the statutory authority under section 337(g)(2) to issue a general exclusion order in an investigation in which all respondents have settled with complainant, and requested briefing on the issues under review. *Id.* Complainant and the IA filed briefs in response to the Commission's notice of review.

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 sections 210.24, 210.43(d), 210.44, and 210.45 of the Commission's rules of practice and procedure (19 CFR 210.24, 210.43(d), 210.44, and 210.45).

By order of the Commission.

Issued: January 21, 2003.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03–1652 Filed 1–23–03; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–485]

Certain Truck Bed Ramps and Components Thereof; Notice of Investigation

AGENCY: International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 20, 2002, under section 337 of the Tarrif Act of 1930, as amended 19 U.S.C. 1337, on behalf of Charles D. Walkden of Homer, Alaska. An amended complaint was filed on January 7, 2003. The complaint, as amended, alleges violations of section 337 in the importation of certain truck bed ramps and components thereof by reason of infringement of claim 1 of U.S. Patent No. 5,795,125. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *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*.

FOR FURTHER INFORMATION CONTACT: Thomas S. Fusco, Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2571.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in § 210.10 of the Commission's rules of practice and procedure, 19 CFR 210.10 (2002).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on January 16, 2003, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain truck bed ramps or components thereof by reason of infringement of claim 1 of U.S. Patent No. 5,795,125, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Charles D. Walkden, 4178 Kachemak Way, Homer, Alaska 99603.

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

ETEC, 2310 Hanselman Avenue, Saskatoon SK, Canada, S7L5Z3.

Textron Inc., 40 Westminister Street, Providence, Rhode Island 02903.

VIP Distributing, 1220 East 68th, Unit 101, Anchorage, Alaska 99518.

Southwest Distributing Co., Highway 183 North, P.O. Box 456, Clinton, Oklahoma 73601.

Hamilton Equipment Inc., 567 South Reading Road, Ephrata, Pennsylvania 17522.

(3) For the investigation so instituted, the Honorable Charles E. Bullock is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with § 210.13 of the Commission's rules of practice and procedure, 19 CFR § 210.13. Pursuant to 19 CFR §§ 201.16(d) and 210.13(a), such responses will be considered by the Commission if received no later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown. Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and to authorize the administrative law judge and the Commission, without further notice to that respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both direct against that respondent.

By order of the Commission.

Issued: January 17, 2003.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03–1613 Filed 1–23–03; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, As Amended

Consistent with Departmental policy, 28 CFR § 50.7, notice is hereby given that on January 7, 2003, a proposed

consent decree in *United States* v. *Town of Middletown,* Civil Action No. 03–011T, was lodged with the United States District Court for the District of Rhode Island. This proposed consent decree resolves the United States' claims on behalf of the Department of the Interior (''DOI'') under the Comprehensive Environment Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9601 *et seq.*, against the Town of Middletown (''the Town'') for response costs that have been or will be incurred at the former Town of Middletown Landfill (''the Site'') located within and adjacent to the Saschuest Point National Wildlife Refuge, Rhode Island.

The constant decree requires the Town to pay $1.5 million to the United States as reimbursement for the past and future costs of the cleanup of the Site.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, PO Box 7611, Washington, DC 20044, and should refer to *United States* v. *Town of Middletown,* D.J. Ref.# 90–11–3–07264.

The proposed consent decree may be examined at the office of the United States Attorney, Fleet Center, 50 Kennedy Plaza, 8th Floor, Providence, RI 02903, and at the Office of the Solicitor, U.S. Department of the Interior, 1849 C. St., NW., Washington, DC 20240–001 (contact John Seymour: (202) 219–3383). A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, PO Box 7611, Washington, DC 20044. In requesting a copy, please enclose a check (there is a 25 cent per page reproduction cost) in the amount of $4.50 payable to the ''U.S. Treasury.''

Ronald G. Gluck,

Assistant Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 03–1584 Filed 1–23–03; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 001–2003]

Privacy Act of 1974; Systems of Records

On November 25, 2002, the President signed into law the Homeland Security Act of 2002, Pub. L. 107–296, 116 Stat. 2135 (2002). Under Title XI, Subtitle B of the Act, the ''authorities, functions, personnel, and assets'' of the Bureau of Alcohol, Tobacco, and Firearms are transferred to the Department of Justice, with the exception of certain enumerated authorities that were retained by the Department of the Treasury. The functions retained by the Department of the Treasury are the responsibility of a new Alcohol and Tobacco Tax and Trade Bureau. Section 1111 of the Homeland Security Act further provides that the Bureau will retain its identity as a separate entity within the Department of Justice known as the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF). The transfer takes effect January 24, 2003.

In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, ATF is publishing its Privacy Act systems of records and converting certain ATF systems of records from Department of the Treasury systems to Department of Justice systems pursuant to the reorganization and transfer of ATF to the Department of Justice.

ATF is designating the following systems of records as Department of Justice systems: ATF–001, Administrative Record System; ATF–003, Criminal Investigation Report System; ATF–006, Internal Security Record System; ATF–007, Personnel Record System; ATF–008, Regulatory Enforcement Record System; ATF–009, Technical and Scientific Services Record System; and ATF–010, Training and Professional Development System. ATF–010, Training and Professional Development Records, is a new notice covering non-federal training participants. ATF–006, Internal Security Record System, was previously published and in effect through 1998, when it was deleted as covered by a Department of the Treasury System notice, Treasury–007, Personnel Security System. Because ATF will no longer be covered by the Treasury notice, the ATF notice for Internal Security Record System–006 is being republished. All other systems notices were previously published by ATF and have been continuously in effect.

There has been no change in the maintenance or operations of the systems of records by ATF. Rather, these systems notices are being published to reflect the transfer of ATF to the Department of Justice. Some revisions were made to update authorities, to clarify certain descriptions of categories, and to revise or add routine uses in accordance with Department of Justice format and practices. A routine use is also being added to allow disclosures to the Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Department of Justice or Department of the Treasury function related to the system of records. Disclosures will not be made under the new system of records or under new routine uses until after the 30-day comment period, except with respect to disclosures to employees of the Alcohol and Tobacco Tax and Trade Bureau who have a need for the records in the performance of their duties during the transition. Such disclosures will be treated as intra-agency disclosures for purposes of section 552a(b)(1) of the Privacy Act.

The publication of these systems of records as Justice systems does not rescind the Treasury/ATF systems of records, as they govern the Alcohol and Tobacco Tax and Trade Bureau within the Department of the Treasury.

Due to the transfer to the Department of Justice, the following Department of Justice Department-wide notices are applicable to ATF: DOJ–001, Accounting Systems for the Department of Justice; DOJ–002, Department of Justice Computer Systems Activity and Access Records; DOJ–003, Correspondence Management Systems for the Department of Justice; DOJ–004, Freedom of Information Act, Privacy Act, and Mandatory Declassification Review Requests and Administrative Appeals for the Department of Justice; DOJ–005, Nationwide Joint Automated Booking System; DOJ–006, Personnel Investigation and Security Clearance Records for the Department of Justice; DOJ–007, Reasonable Accommodations for the Department of Justice; Justice/JMD–005, Grievance Records; Justice/JMD–017, Department of Justice Employee Transportation Facilitation System; Justice/JMD–012, Department of Justice Call Detail Records and Justice/DAG–011, Miscellaneous Attorney Personnel Records System.

A comment period will be held for the systems of records published by ATF today. In accordance with 5 U.S.C. 552(e)(4) and (11), the public is given a 30-day period in which to comment; and the Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to conclude its review of the systems. Therefore, please submit any comments by February 24, 2003. The public, OMB, and Congress are invited to submit any comments to Mary E. Cahill, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 1400 National Place Building).

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and the Congress.

Dated: January 17, 2003.

Paul R. Corts,

Assistant Attorney General for Administration.

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ATF–001—Administrative Record System
ATF–003—Criminal Investigation Report System
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ATF–009—Technical and Scientific Services Record System
ATF–010—Training and Professional Development Record System

JUSTICE/ATF–001

SYSTEM NAME:

Administrative Record System-Justice/ATF–001.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this record system are geographically dispersed throughout the Bureau's field offices. A list of field offices is available by writing to the Chief, Disclosure Division, Room 8400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Present employees of the Bureau of ATF. (2) Former employees of the Bureau of ATF. (3) Claimants against the Bureau of ATF.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents related to claims submitted including: (1) Accident Report—vehicle; (2) Fatality reports; (3) Injury reports; (4) Chief Counsel and District Counsel memoranda and opinions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

(1) Federal Claims Collection Act. (2) Federal Property and Administration Services Act of 1949, as amended. (3) Federal Tort Claims Act. (4) Military Personnel and Civilian Claims Act. (5) Occupational Safety and Health Act of 1970. (6) Small Claims Act. (7) 5 U.S.C. 1302, 3301, 3302.

PURPOSE(S):

The purpose of this system is to resolve claims submitted to the Bureau of Alcohol, Tobacco, Firearms and Explosives.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations to the extent necessary to obtain relevant information needed by the Bureau to render a decision in regard to an administrative matter.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To unions recognized as exclusive bargaining representatives in accordance with provisions contained in the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114.

P. To complainants and/or victims to the extent necessary to provide such persons with information and explanations concerning the progress and/or results of the investigation or case arising from the matters of which they complained and/or of which they were a victim.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Active records are stored in file folders in security filing cabinets. Inactive records are stored in file folders at Federal Records Centers. Records are also stored in electronic media.

RETRIEVABILITY:

Records are retrieved by name of individual.

SAFEGUARDS:

Direct access is restricted to personnel in the Department of Justice in the

performance of their duty. Records are transmitted to routine users on a need to know basis or where a right to access is established, and to others upon verification of the substance and propriety of the request. These records are stored in lockable metal file cabinets in rooms locked during non-duty hours. The records stored in electronic media are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules Numbers 1 through 23 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives records control schedules numbers 101 and 201 and disposed of by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Office of Management/Chief Financial Officer, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

For records accessible through the Privacy Act, a request should be made in writing and mailed to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. The envelope and the letter should be clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed, dated, and either notarized or submitted under penalty of perjury.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information.

RECORD SOURCE CATEGORIES:

(1) Administrative records; (2) Claimants; (3) Doctors; (4) Employee records; (5) Fiscal records; (6) Former employees of the Bureau of ATF; (7) Former employers; (8) General Services Administration; (9) Individuals who have information relevant to claims; (10) Inspections records; (11) Internal Investigation reports; (12) Police reports; (13) Present employees of the Bureau of ATF; (14) Supervisors; (15) Witnesses; (16) Insurance companies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

JUSTICE/ATF–003

SYSTEM NAME:

Criminal Investigation Report System, Justice/ATF–003.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this record system are geographically dispersed throughout Bureau of Alcohol, Tobacco, Firearms and Explosives' field offices. A list of field offices is available by writing to the Chief, Disclosure Division, Room 8400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Criminal offenders or alleged criminal offenders acting alone or in concert with other individuals and suspects who have been or are under investigation for a violation or suspected violation of laws enforced by the Bureau; (2) Criminal offenders or alleged criminal offenders acting alone or in concert with individuals who have been referred to the Bureau of Alcohol, Tobacco, Firearms and Explosives by other law enforcement agencies, governmental units or the general public; (3) Informants; (4) Persons who come to the attention of the Bureau in the course of criminal investigations; (5) Persons who have been convicted of a crime punishable by imprisonment for a term exceeding one year and who have applied for relief from disabilities under Federal law with respect to the acquisition, receipt, transfer, shipment, or possession of firearms and explosives and whose disability was incurred by reason of such conviction; (6) Victims of crimes; (7) Witnesses.

CATEGORIES OF RECORDS IN THE SYSTEM:

(a) Records containing information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting of identifying data and notations of arrest, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (b) Records containing information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; (c) Records containing reports identifiable to an individual compiled at various stages of the process of enforcement of criminal laws from arrest or indictment through release from supervision; (d) Records compiled and maintained by the Bureau as generally described in (a), (b), and (c) above including the following: (1) Abandoned property reports; (2) ATF Criminal Investigation Reports; (3) ATF referrals to foreign, Federal, state, and local law enforcement agencies; (4) Chief and Regional Counsel opinions; (5) Contemporaneous investigative notes; (6) Criminal investigatory correspondence from and to foreign, Federal, state and local law enforcement agencies; (7) Criminal intelligence information on individuals suspected to be violating ATF laws and regulations; (8) Documentary proof of defendant's criminal record, identity, or lack of registration of National Firearms Act (N.F.A.) (as amended) firearm(s); (9) FBI Criminal Record Reports; (10) Fingerprints and palmprints; (11) Fugitive arrest warrants; (12) Handwriting exemplars; (13) Records of violations and reputation; (14) Illicit liquor and raw material surveys; (15) Laboratory reports of evidence analysis; (16) Memoranda of expected testimony of witnesses; (17) Organized crime members violating or suspected of violating ATF laws; (18) Parole and pardon reports; (19) Personal histories (address, employment, social security number, financial background, physical description, *etc.*); (20) Photographs; (21) Purchase of evidence records; (22) Records of electronic surveillance by ATF; (23) Records received in response to summons and subpoenas; (24) Reliefs from disability; (25) Reports of interview with witnesses; (26) Search warrants and affidavits for search warrants; (27) Seized property reports; (28) Criminal records concerning firearms, explosives and alcohol; (29) Special agent's daily activity diary (accessible by date only); (30) State and local law enforcement criminal investigative reports; (31) Statements of defendants; (32) Statements of witnesses; (33) Summons and subpoenas issued pursuant to criminal investigations; (34) Voice prints; (35) Wagering tax suspected violators; (36) Warning and demand letters; (37) Criminal violation reports (a formal report compiling all or portions of the foregoing for prosecutive purposes).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

(1) 26 U.S.C. Chapter 40; (2) 26 U.S.C. Chapter 53, as amended; (3) 26 U.S.C. Chapters 61 through 80, as amended; (4) 18 U.S.C. Chapter 40; (5) 18 U.S.C. Chapter 44; (6) 18 U.S.C. Chapter 59; (7) 18 U.S.C. Chapter 114; (8) 22 U.S.C. 227; (9) 18 U.S.C. 1952; (10) Public Law 107–296.

PURPOSE(S):

The purpose of this system is to suppress traffic in distilled spirits and tobacco products on which taxes have not been paid; to enforce the Federal laws relating to the illegal possession and use of firearms, destructive devices, explosives, explosive materials; and to assist Federal, state, local and foreign law enforcement agencies in reducing crime and violence.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. To appropriate federal, state, local, foreign, or tribal law enforcement authorities for law enforcement purposes—criminal, civil, or regulatory.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations in the course of an investigation to the extent necessary to obtain information pertinent to the investigation.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To criminal or national security intelligence gathering organizations for the purpose of identifying and suppressing the activities of international and national criminals and terrorists.

P. To insurance companies making determinations regarding claims in cases where the Bureau has conducted or is conducting an arson investigation.

Q. To unions recognized as exclusive bargaining representatives in accordance with provisions contained in the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114.

R. To complainants and/or victims to the extent necessary to provide such persons with information and explanations concerning the progress and/or results of the investigation or case arising from the matters of which they complained and/or of which they were a victim.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Active records are stored in file folders in secure filing cabinets. Inactive records are stored in file folders at Federal Records Centers. Records are also stored in electronic media.

RETRIEVABILITY:

Records are retrieved by name, date of birth, social security number, other unique identifier, investigation number, serial number of firearm, or a combination of any of these; plus date and geographical location of incident giving rise to investigation.

SAFEGUARDS:

Direct access restricted to personnel in the Department of Justice in the performance of their duty. Transmitted to routine users on a need to know basis and to others upon verification of the substance and propriety of the request. Stored in lockable file cabinets in rooms locked during non-duty hours. The records stored in electronic media are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules numbers 1 through 23 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives Records Control Schedules numbers 101 and 201 and disposed of by shredding or burning. Records on tape or on-line mass storage are disposed of by degaussing.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Firearms Explosive & Arson; Assistant Director, Field Operations; and Assistant Director, Science & Technology, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

For Records Accessible through the Privacy Act, mail a request in writing to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW.,

Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and dated and either notarized or submitted under penalty of perjury. Some information may be exempt from access provisions as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may access those records that are not exempt from disclosure. A determination whether a record may be accessed will be made at the time a request is received.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information. Some information may be exempt from contesting record procedures as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may amend those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

RECORD SOURCE CATEGORIES:

Categories of individuals covered by the system: (1) Federal, state and local agencies; (2) witnesses; (3) employers; (4) professional organizations; (5) victims; (6) criminal offenders or alleged criminal offenders; (7) fiscal records; (8) inspection records; (9) investigation records; (10) persons having knowledge of potential criminal activity; and (11) other persons listed in ''Categories of individuals covered by the system'' in this notice.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(j)(2), the Attorney General has exempted records in this system from subsections (c)(3) and (4), (d)(1), (2),(3) and (4), (e)(1), (2) and (3), (e)(4)(G), (H), and (I), (e)(5) and (8), (f) and (g) of the Privacy Act. Rules have been promulgated in accordance with the requirement of 5 U.S.C. 553(b), (c) and (e) and are published in today's **Federal Register**.

JUSTICE/ATF.006

SYSTEM NAME:

Internal Security Record System-Justice/ATF–006.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Present employees of the Bureau of ATF; (2) Former employees of the Bureau of ATF; (3) Applicants for employment; (4) Non-Bureau employees involved in criminal acts toward Bureau employees and Bureau property; (5) Individuals who were interviewed by Internal Affairs Special Agents; (6) Contract employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Records containing investigative material compiled for law enforcement purposes including information relating to: (a) Conduct of employees and contract employees; (b) Integrity of employees; (2) Records containing investigative material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment or access to classified information including reports relating to security clearances of employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

18 U.S.C. 201, Executive Order 10450, Executive Order 11222.

PURPOSE(S):

This system is used to assure the Bureau Director, the Department of Justice, and the public that the Bureau is taking strong and vigorous steps to maintain the highest standards of integrity, loyalty, conduct, and security among Bureau personnel and contract employees. When a criminal investigation results in a compilation of information contained in this system, the information so compiled shall be transferred to the ATF Criminal Investigation Report System and shall become a part of that system for all purposes of the Privacy Act of 1974.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for

personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations in the course of an investigation to the extent necessary to obtain information pertinent to the investigation.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To unions recognized as exclusive bargaining representatives in accordance with provisions contained in the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114.

P. To complainants and/or victims to the extent necessary to provide such persons with information and explanations concerning the progress and/or results of the investigation or case arising from the matter of which they complained and/or of which they were a victim.

Q. To designated officers and employees of state or local (including the District of Columbia) law enforcement or detention agencies in connection with the hiring or continued employment of an employee or contractor, where the employee or contractor would occupy or occupies a position of public trust as a law enforcement officer or detention officer having direct contact with the public or with prisoners or detainees, to the extent that the information is relevant and necessary to the recipient agency's decision.

R. To the Office of Personnel Management, Merit Systems Protection Board, Equal Employment Opportunity Commission, Federal Labor Relations Authority, and the Office of Special Counsel for the purpose of properly administering Federal personnel systems or other agencies' systems in accordance with applicable laws, Executive Orders, and regulations.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Active records stored in file folders in security filing cabinets and computer system (hard disk). Inactive records stored in file folders at Federal Records Center.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Direct access restricted to personnel in Department of the Justice in the performance of their duty. Transmitted to routine users on a need to know basis and to others upon verification of the substance and propriety of the request. Stored in lockable metal file cabinets in rooms locked during non-duty hours.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules Numbers 1 through 20 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives Records Control Schedules numbers 101 and 201 and disposed of by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director (Office of Inspection), Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, N.W., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

For records accessible through the Privacy Act, address a request in writing to Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed, dated and either notarized or submitted under penalty of perjury. Some information may be exempt from access provisions as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may access those records that are not exempt from disclosure. A determination whether a record may be accessed will be made at the time a request is received.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information. Some information may be exempt from contesting record procedures as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may amend those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

RECORD SOURCE CATEGORIES:

Examples include: (1) Employees of this Bureau; (2) Internal Investigative report forms; (3) Witnesses; (4) Informants; (5) Federal, state and local enforcement agencies; (6) Employers; (7) Educational institutions; (8) Credit agencies; (9) Neighbors; (10) References; (11) Professional Organizations; (12) Other government agencies; (13) Claimants; (14) Victims.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5) (relating to security clearances) and (k)(2) (relating to conduct and integrity), the Attorney General has exempted records in this system from subsections (c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act. Rules have been promulgated in accordance with the requirement of 5 U.S.C. 553(b), (c) and (e) and are published in today's **Federal Register**.

JUSTICE/ATF–007

SYSTEM NAME:

Personnel Record System-Justice/ATF–007

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this record system are geographically dispersed throughout the Bureau's field offices. A list of field offices is available by writing to the Chief, Disclosure Division, Room 8400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Present Employees of the Bureau of ATF; (2) Former Employees of the Bureau of ATF; (3) Applicants for employment with ATF.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include: (1) Allotment and Dues; (2) Annual Tax Reports; (3) Applicants for employment; (4) Applications for reassignment; (5) Awards, honors, and fellowship records; (6) Classification appeal records; (7) Death claim records; (8) Educational history; (9) Employee indebtedness records; (10) Employees qualified as Grievance Examiners; (11) Employee Suggestions; (12) Employee history; (13) Employee relations case file; (14) Equal employment opportunity records; (15) Health maintenance records; (16) Insurance records; (17) Military history; (18) Occupational injuries, disabilities, and Worker's Compensation Records; (19) Official personnel folder; (20) Outside employment and identification numbers, business or professional records; (21) Outside employment; (22) Outside financial interests; (23) Overtime and/or Premium Pay records; (24) Performance evaluation records; (25) Personal history; (26) Position description records; (27) Promotion/Selection Certificates Records; (28) Property custody records; (29) Retirement records; (30) Records of security clearance; (31) Statement of career goals; (32) Supervisory or managerial potential records; (33) Temporary assignments and details; (34) Time application reports and records; (35) Training record; (36) U.S. Savings Bond participation records; (37) Upward mobility applications; (38) Vehicle accidents; (39) Withholding tax records; (40) Work schedule records; (41) Chief Counsel and Regional Counsel memoranda and opinions; (42) Government passport records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

(1) 5 U.S.C. Chapter 29, Subchapter II; (2) 5 U.S.C. Chapters 31 and 33; (3) 5 U.S.C. Chapter 43; (4) 5 U.S.C. Chapter 45; (5) 5 U.S.C. Chapter 51; (6) 5 U.S.C. Chapter 55, subchapter III; (7) 5 U.S.C. Chapter 61; (8) 5 U.S.C. Chapter 75; (9) 5 U.S.C. Chapter 83; (10) 5 U.S.C. 301; 31 CFR 2.28; 5 CFR 550.122, 550.183; (11) 5 U.S.C. 4503; (12) 5 U.S.C. 5101–5115; (13) 5 U.S.C. 7151–7154; (14) 5 U.S.C. 7901; (15) Public Law 92–261 (Equal Employment Act of 1972); (16) Public Law 93–579; (Federal Employees Compensation Act); (17) Occupational Safety and Health Act of 1970; (18) Executive Order 10561; (19) Executive Order 11222; (20) Executive Order 11478; (21) Executive Order 11491.

PURPOSE(S):

The purpose of this system is to provide a source of factual data about a person's Federal employment while in the service of the Bureau of Alcohol, Tobacco, Firearms and Explosives.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations to the extent necessary to obtain relevant information needed by the Bureau to render a decision in regard to a personnel matter.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To unions recognized as exclusive bargaining representatives in accordance with provisions contained in the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Active records are stored in file folders in security filing cabinets. Inactive records are stored in file folders at Federal Records Centers. Records are also stored in electronic media.

RETRIEVABILITY:

Records are retrieved by name, date of birth, social security number, employee identification number, or a combination of any of these four.

SAFEGUARDS:

Direct access is restricted to personnel in the Department of Justice in the performance of their duty. Records are transmitted to routine users on a need to know basis or where a right to access is established, and to others upon verification of the substance and propriety of the request. These records are stored in lockable file cabinets in rooms locked during non-duty hours. The records stored in electronic media are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules numbers 1 through 23 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives Records Control Schedules numbers 101 and 201 and disposed of by shredding, burning or by degaussing.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Office of Science and Technology; Assistant Director, Public and Governmental Affairs; and Assistant Director, Management/Chief Financial Officer, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

For records accessible through the Privacy Act, mail a request in writing to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed, dated, and either notarized or submitted under penalty of perjury. Some information may be exempt from access provisions as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may access those records that are not exempt from disclosure. A determination whether a record may be accessed will be made at the time a request is received.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information. Some information may be exempt from contesting record procedures as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may amend those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

RECORD SOURCE CATEGORIES:

Examples include: (1) Administrative Records; (2) Applicants for employment with the Bureau; (3) Acquaintances; (4) Business and professional associates; (5) Creditors; (6) Criminal records; (7) Educational Institutions attended; (8) Employee records; (9) Equal Employment Opportunity Commission; (10) Financial institutions; (11) Fiscal records; (12) Former employees; (13) Former employers; (14) Inspection records; (15) Internal investigation reports; (16) Internal Revenue Service; (17) Military records; (18) Outside employers; (19) Physicians; (20) Police reports; (21) Position classification specialists; (22) Psychiatrists; (23) References; (24) Supervisors; (25) Training officers; (26) Unions, accredited; (27) Office of Personnel Management; (28) Witnesses.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5) the Attorney General has exempted records in this system from subsections (c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act. Rules have been promulgated in accordance with the requirement of 5 U.S.C. 553(b), (c) and (e) and are published in today's **Federal Register**.

JUSTICE/ATF–008

SYSTEM NAME:

Regulatory Enforcement Record System—Justice/ATF–008.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this system of records are also geographically dispersed throughout ATF's district and field offices. A list of field offices is available by writing to the Chief, Disclosure Division, Room 8400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have been issued permits or licenses, have filed applications with ATF, have registered with ATF, or are responsible persons or employees of a licensee or permittee to the extent that the records concern private individuals or entrepreneurs, including, but not limited to: (a) Explosives licensees, employees and responsible persons; (b) Claimants for refund of taxes; (c) Federal Firearms Licenses, employees and responsible persons (d) Collectors of firearms or ammunition; (e) Importers of firearms or ammunition, and (f) Users of explosive materials.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records containing investigative material compiled for law enforcement purposes which may consist of the following: (1) Abstracts of offers in compromise; (2) Administrative law judge decisions; (3) Assessment records: (a) notices of proposed assessments, (b) notices of shortages or losses, (c) notices to IRS to assess taxes, (d) recommendation for assessments, (4) Claim records: (a) claims; (b) letters of claim rejection; (c) sample reports; (d) supporting data; (e) vouchers and schedules of payment; (5) Comments on proposed rulemakings; (6) Complaints from third parties; (7) Correspondence concerning records in this system and related matters; (8) Financial statements; (9) Inspection and investigation reports; (10) Joint demands on principals and sureties for payment of excise tax liabilities; (11) Letters of reprimand; (12) Lists of permittees and licensees; (13) Lists of officers, directors and principal stockholders; (14) Mailing lists and addressograph plates; (15) Notices of delinquent reports; (16) Offers in compromise; (17) Operation records: (a) operating reports, (b) reports of required inventories, (c) reports of thefts or losses of firearms, (d) reports of thefts of explosive materials, (e) transaction records, (f) transaction reports; (18) Orders of revocation, suspension or annulment of permits or licenses; (19) District and Chief Counsel opinions and memoranda; (20) Reports of violations; (21) Permit status records; (22) Qualifying and background records: (a) access authorizations, (b) advertisement records, (c) applications, (d) bonds, (e) business histories, (f) criminal records, (g) diagrams of premises, (h) educational histories, (i) employment histories, (j) environmental records, (k) financial data, (l) formula approvals, (m) label approvals, (n) licenses, (o) notices, (p) permits, (q) personal references, (r) plant profiles, (s) plant capacities, (t)

plats and plans, (u) registrations, (v) sample reports, (w) signature authorities, (x) special permissions and authorizations, (y) statements of process; (23) Show cause orders; (24) Tax records: (a) control cards relating to periodic payment and prepayment of taxes, (b) excise and special tax returns, (c) notices of tax discrepancy or adjustment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

(1) 26 U.S.C. 7011; (2) 18 U.S.C. 923(a); (3) 18 U.S.C. 923(b); (4) 18 U.S.C. 843(a); (5) 22 U.S.C. 2278; (6) 26 U.S.C. 6001; (7) 26 U.S.C. 6011(a); (8) 26 U.S.C. 6201; (9) 26 U.S.C. 7122; (10) 18 U.S.C. 843(d); (11) 18 U.S.C. 923(f); (12) Pub. L. 107–296.

PURPOSE(S):

The purpose of this system is to determine suitability, eligibility or qualifications of individuals who are engaged or propose to engage in activities regulated by ATF; achieve compliance with laws under ATF's jurisdiction; interact with Federal, state and local governmental agencies in the resolution of problems relating to industrial development, revenue protection, public health, ecology, and other areas of joint jurisdictional concern. When a criminal investigation results in a compilation of information contained in this system of records, the information shall be transferred to the Justice/ATF—Criminal Investigation Report System and shall become part of that system for all purposes of the Privacy Act of 1974.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations to the extent necessary to obtain or verify information pertinent to the Bureau's decision to grant, deny or revoke a license or permit, or pertinent to an ongoing investigation.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To national and international intelligence gathering organizations for the purpose of identifying international and national criminals involved in consumer fraud, revenue evasion or crimes.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders in filing cabinets and in electronic media.

RETRIEVABILITY:

Records are retrieved by name, permit or license number, by document locator number, or by employer identification number (EIN).

SAFEGUARDS:

Direct access restricted to personnel in the Department of Justice in the performance of their duty. Transmitted to routine users on a need to know basis and others upon verification of the substance and propriety of the request. Stored in file cabinets in rooms locked during non-duty hours. The records stored in electronic media are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules numbers 1 through 20 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives Records Control Schedules numbers 101 and 201 and disposed of by shredding, burning or by degaussing.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Firearms Explosive & Arson; Field Operations; and Assistant Director, Science & Technology, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES

For Records Accessible through the Privacy Act, mail a written request to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed, dated, and either notarized or submitted under penalty of perjury. Some information may be exempt from access provisions as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may access those records that are not exempt from disclosure. A determination whether a record may be accessed will be made at the time a request is received.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information. Some information may be exempt from contesting record procedures as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may amend those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

RECORD SOURCE CATEGORIES:

Examples include: (1) Acquaintances; (2) Bureau personnel; (3) Business and professional associates; (4) Creditors; (5) Criminal records; (6) Financial institutions; (7) Former employers; (8) Internal Revenue Service; (9) Military records; (10) Physicians; (11) Psychiatrists; (12) References; (13) Police reports; (14) Witnesses; (15) Federal law enforcement agencies; (16) State law enforcement agencies; (17) Local law enforcement agencies; (18) State regulatory agencies; (19) Federal regulatory agencies; (20) Local regulatory agencies; (21) Chief Counsel's opinions; (22) Regional Counsel's opinions; (23) Chief Counsel's memoranda; (24) Regional Counsel's memoranda; (25) Field investigation reports; (26) Third parties.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(2), the Attorney General has exempted records in this system from subsections (c)(3), (d)(1), (2), (3) and (4), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act. Rules have been promulgated in accordance with the requirement of 5 U.S.C. 553(b), (c) and (e) and are published in today's **Federal Register**.

JUSTICE/ATF–009

SYSTEM NAME:

Technical and Scientific Services Record System Justice/ATF–009.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this record system are geographically dispersed throughout Bureau of Alcohol, Tobacco, Firearms and Explosives' field offices. A list of field offices is available by writing to the Chief, Disclosure Division, Room 8400, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered may include: (1) Applicants to register firearms under the National Firearms Act; (2) Importers of implements of war as defined under the Mutual Security Act of 1954 and the Arms Export Control Act of 1976; (3) Licensed importers registered under the Mutual Security Act of 1954 and the Arms Export Control Act of 1976; (4) Manufacturers of National Firearms Act firearms that are exempt from payment of Special (Occupational) tax provisions; (5) Non-Bureau chemists certified to make analysis of alcoholic beverages; (6) Persons involved in explosives tagging and detection program; (7) Registered owners of National Firearms Act firearms; (8) Special (Occupational) taxpayers as defined under Title II of the Gun Control Act of 1968; (9) Victims of explosives; (10) Individuals involved in Government funded research projects.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include: (1) Alteration records of registered National Firearms Act firearms; (2) Applications to register firearms and destructive devices under the National Firearms Act; (3) Applications to import articles on the United States Munitions list; (4) Blueprints; (5) Certifications of payment of Special (occupational) tax payments; (6) Changes of address for owner of firearms registered under the National Firearms Act; (7) Claims for erroneous Special (Occupational) taxes payments; (8) Descriptions of Inventions; (9) Delinquency notices regarding proof of importation of National Firearms Act firearms; (10) Explosive reports; (11) Non-Bureau chemists' statements of qualification; (12) Patent information; (13) Registrations of firearms and destructive devices under the National Firearms Act; (14) Registration of war trophy firearms; (15) Requests and authorizations for temporary movement and/or temporary storage of National Firearms Act firearms; (16) Technical and scientific data; (17) Transaction records concerning National Firearms Act firearms; (18) Trade secrets; (19) United States Government contracts to manufacturers of National Firearms Act firearms; (20) Chief Counsel and Regional Counsel memoranda and opinions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

(1) 18 U.S.C. Chapter 40; (2) 18 U.S.C. Chapter 44; (3) 26 U.S.C. 6001(a); (4) 26 U.S.C. 6201; (5) 26 U.S.C. 7011; (6) Executive Order 11958; (7) Public Law 107–296.

PURPOSE(S):

The purpose of this system is to provide technical, investigative and scientific support and expertise to Criminal and Regulatory Enforcement activities of the Bureau; to other Federal, state, local and foreign law enforcement agencies; and to provide scientific support and expertise to those industries involved in activities regulated by the Bureau. When a criminal investigation results in a compilation of information contained in this system, the information so compiled shall be transferred to the Justice/ATF—Criminal Investigation Report System and shall become a part of that system for all purposes of the Privacy Act of 1974.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to

accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations to the extent necessary to obtain or verify information pertinent to the Bureau's decision to grant, deny, or revoke a license or permit, or pertinent to an ongoing investigation.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To insurance companies making determinations regarding claims in cases where the Bureau has conducted or is conducting an arson investigation.

P. To national and international intelligence gathering organizations for the purpose of identifying international and national criminals involved in consumer fraud, revenue evasion or crimes.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and in electronic media.

RETRIEVABILITY:

Records are retrieved by name, by other unique identifier, control number, serial number of National Firearms Act firearms.

SAFEGUARDS:

Records are stored in file cabinets locked during non-duty hours. The records stored in electronic media are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules numbers 1 through 20 issued by the National Archives and Records Administration, and Bureau of Alcohol, Tobacco, Firearms and Explosives Records Control Schedules numbers 101 and 201 and disposed of by shredding or burning. Records stored on tape discs or on-line mass storage are disposed of by degaussing.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Firearms Explosive & Arson; Assistant Director, Field Operations; and Assistant Director, Science & Technology, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

If records are accessible through the Privacy Act, mail a written request to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed, dated, and either notarized or submitted under penalty of perjury. Some information may be exempt from access provisions as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may access those records that are not exempt from disclosure. A determination whether a record may be accessed will be made at the time a request is received.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information. Some information may be exempt from contesting record procedures as described in the section entitled ''Exemptions claimed for the system.'' An individual who is the subject of a record in this system may amend those records that are not exempt. A determination whether a record may be amended will be made at the time a request is received.

RECORD SOURCE CATEGORIES:

Examples include: (1) Individuals; (2) Companies; (3) Corporations; (4) Firearms Licensees; (5) Explosive Licensees; (6) Explosive Permittees; (7) Bureau personnel; (8) Federal law enforcement agencies; (9) State law enforcement agencies; (10) Local law enforcement agencies; (11) Foreign law enforcement agencies; (12) Federal

Regulatory agencies; (13) State Regulatory agencies; (14) Local Regulatory agencies; (15) Non-Bureau Chemists.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(2), the Attorney General has exempted records in this system from subsections (c)(3), (d)(1), (2),(3) and (4), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act. Rules have been promulgated in accordance with the requirement of 5 U.S.C. 553(b), (c) and (e) and are published in today's **Federal Register**.

JUSTICE/ATF–010

SYSTEM NAME:

Training and Professional Development Record System-Treasury/ATF–010.

SYSTEM LOCATION:

Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226. Components of this record system are geographically dispersed throughout the Bureau's field offices. A list of field offices is available by writing to the Chief, Disclosure Division, 650 Massachusetts Avenue, NW., Washington, DC 20226.

CATEGORIES OF INDIVIDUALS COVERED IN THE SYSTEM:

Non-ATF individuals applying for ATF training and/or professional development; those instructors for ATF training and/or professional development; possible emergency contacts and/or supervisors' names are collected from the trainee.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include: (a) Name, (b) office address, (c) telephone number, (d) fax number, (e) social security information, (f) firearms qualifications, (g) eligibility of instructors, (h) certifications held by instructors, (i) courses previously taught by instructors, (j) home address, date of birth, (k) position title, (l) length of time in public service, (m) time on current assignment, number of years in current position, (n) name and telephone number of immediate supervisor, (o) education experience, (p) related occupational experience, (q) blood type, (r) military experience, (s) law enforcement experience, (t) description of duties and responsibilities, (u) internet address, (v) pager number, (w) smoking preference, (x) Chief Counsel and Regional Counsel memoranda and opinions, and (y) other information as needed or required for training or instructor determination or safety.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 4104; Executive Order No. 11348 as amended by Executive Order No. 12107 (1978).

PURPOSE(S):

The purpose of this system is to provide basic data about ATF instructors and those trained by ATF.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:

A record in this system may be disclosed as a routine use:

A. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

B. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records.

C. In the event that a record in this system, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, foreign, or tribal law enforcement authority or other appropriate agency charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

D. To officials and employees of a federal agency or entity, including the White House, which requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the issuance of a security clearance; the execution of a security or suitability investigation; the classification of a job; or the issuance of a grant or benefit.

E. In an appropriate proceeding before a court or administrative or regulatory body when records are determined by the Department of Justice to be arguably relevant to the proceeding.

F. To an actual or potential party to litigation or the party's authorized representative for the purpose of negotiation or discussion on such matters as settlement, plea bargaining, or in informal discovery proceedings.

G. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

H. To federal, state, and local licensing agencies or associations, which require information concerning the suitability or eligibility of an individual for a license or permit.

I. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

J. To a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To such recipients and under such circumstances and procedures as are mandated by federal statute or treaty.

L. To an organization or individual in either the public or private sector where there is reason to believe the recipient is or could become the target of a particular criminal activity or conspiracy, to the extent the information is relevant to the protection of life or property.

M. To individuals and organizations to the extent necessary to verify their qualifications or eligibility for training.

N. To Treasury Department, Alcohol and Tobacco Tax and Trade Bureau employees, when necessary to accomplish a Treasury Department or Department of Justice function related to this system of records.

O. To unions recognized as exclusive bargaining representatives in accordance with provisions contained in the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in security filing cabinets. Records are also stored in electronic media.

RETRIEVABILITY:

Records are retrieved by name, agency and/or office location, social security number or any of the above.

SAFEGUARDS:

Paper records are kept in locked filing cabinets in locked rooms during non-business hours. Electronic media records are password protected.

RETENTION AND DISPOSAL:

Records are retained in accordance with General Records Schedules numbers 1 through 23 issued by the National Archives and Records Administration, and the Bureau of Alcohol, Tobacco, Firearms and Explosives Control Schedules number 101 and 201 and disposed of by shredding, burning or by degaussing.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Training and Professional Development, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226.

NOTIFICATION PROCEDURE:

See ''Record access procedures'' below.

RECORD ACCESS PROCEDURES:

For records accessible through the Privacy Act, mail a request in writing to the Disclosure Division, Privacy Act Request, Bureau of Alcohol, Tobacco, Firearms and Explosives, 650 Massachusetts Avenue, NW., Washington, DC 20226, with the envelope and the letter clearly marked ''Privacy Access Request.'' The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and dated and either notarized or submitted under penalty of perjury.

CONTESTING RECORD PROCEDURES:

Individuals desiring to contest or amend information maintained in the system should direct their request according to the Record Access procedures listed above, stating clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information sought. Some information is not subject to amendment, such as tax return information.

RECORD SOURCE CATEGORIES:

Examples include: Administrative records, applications submitted by non-ATF individuals seeking ATF training and applications submitted by instructors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 03–1576 Filed 1–23–03; 8:45 am]

BILLING CODE 4410–FB–P

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages 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, contain 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.

Withdrawn General Wage Determination Decisions

This is to advise all interested parties that the Department of Labor is withdrawing, from the date of this notice, General Wage Decisions as listed below.

MS020057 See MS020056
OR020017 See OR020003

Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c)(2)(i)(A), when the opening of bids is less than ten (10) days from the date of this notice, this action shall be effective unless the agency finds that there is insufficient time to notify bidders of the change and the finding is documented in the contract file.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations 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

Connecticut
CT020001 (Mar. 1, 2002)

Volume II

Pennsylvania
PA020001 (Mar. 1, 2002)
PA020002 (Mar. 1, 2002)
PA020003 (Mar. 1, 2002)
PA020004 (Mar. 1, 2002)
PA020005 (Mar. 1, 2002)
PA020006 (Mar. 1, 2002)
PA020007 (Mar. 1, 2002)
PA020008 (Mar. 1, 2002)
PA020009 (Mar. 1, 2002)
PA020010 (Mar. 1, 2002)
PA020013 (Mar. 1, 2002)
PA020014 (Mar. 1, 2002)
PA020016 (Mar. 1, 2002)
PA020017 (Mar. 1, 2002)
PA020018 (Mar. 1, 2002)
PA020019 (Mar. 1, 2002)
PA020020 (Mar. 1, 2002)
PA020021 (Mar. 1, 2002)
PA020023 (Mar. 1, 2002)
PA020024 (Mar. 1, 2002)
PA020025 (Mar. 1, 2002)
PA020026 (Mar. 1, 2002)
PA020027 (Mar. 1, 2002)
PA020029 (Mar. 1, 2002)
PA020030 (Mar. 1, 2002)
PA020031 (Mar. 1, 2002)
PA020032 (Mar. 1, 2002)
PA020035 (Mar. 1, 2002)
PA020038 (Mar. 1, 2002)
PA020040 (Mar. 1, 2002)
PA020042 (Mar. 1, 2002)
PA020051 (Mar. 1, 2002)
PA020052 (Mar. 1, 2002)
PA020053 (Mar. 1, 2002)
PA020054 (Mar. 1, 2002)
PA020055 (Mar. 1, 2002)
PA020059 (Mar. 1, 2002)
PA020060 (Mar. 1, 2002)
PA020061 (Mar. 1, 2002)
PA020065 (Mar. 1, 2002)

Volume III

Florida
FL020001 (Mar. 1, 2002)
FL020009 (Mar. 1, 2002)
FL020016 (Mar. 1, 2002)
FL020017 (Mar. 1, 2002)
FL020032 (Mar. 1, 2002)
FL020034 (Mar. 1, 2002)
FL020046 (Mar. 1, 2002)
FL020076 (Mar. 1, 2002)
FL020100 (Mar. 1, 2002)
Georgia
GA020053 (Mar. 1, 2002)
Mississippi
MS020055 (Mar. 1, 2002)
MS020056 (Mar. 1, 2002)

Volume IV

Wisconsin
WI020011 (Mar. 1, 2002)

Volume V

Kansas
KS020007 (Mar. 1, 2002)
KS020009 (Mar. 1, 2002)
KS020010 (Mar. 1, 2002)
KS020011 (Mar. 1, 2002)
KS020012 (Mar. 1, 2002)
KS020013 (Mar. 1, 2002)
KS020016 (Mar. 1, 2002)
KS020018 (Mar. 1, 2002)
KS020019 (Mar. 1, 2002)
KS020020 (Mar. 1, 2002)
KS020021 (Mar. 1, 2002)
KS020023 (Mar. 1, 2002)
KS020025 (Mar. 1, 2002)
KS020026 (Mar. 1, 2002)
KS020029 (Mar. 1, 2002)
KS020035 (Mar. 1, 2002)
KS020069 (Mar. 1, 2002)
KS020070 (Mar. 1, 2002)
Missouri
MO020001 (Mar. 1, 2002)
MO020013 (Mar. 1, 2002)
MO020015 (Mar. 1, 2002)
MO020020 (Mar. 1, 2002)
MO020042 (Mar. 1, 2002)
MO020044 (Mar. 1, 2002)
MO020054 (Mar. 1, 2002)
MO020058 (Mar. 1, 2002)
Oklahoma
OK020013 (Mar. 1, 2002)
OK020015 (Mar. 1, 2002)
OK020016 (Mar. 1, 2002)
OK020018 (Mar. 1, 2002)
OK020034 (Mar. 1, 2002)
OK020035 (Mar. 1, 2002)
OK020036 (Mar. 1, 2002)
OK020037 (Mar. 1, 2002)
OK020038 (Mar. 1, 2002)
Texas
TX020003 (Mar. 1, 2002)
TX020007 (Mar. 1, 2002)
TX020010 (Mar. 1, 2002)
TX020015 (Mar. 1, 2002)
TX020055 (Mar. 1, 2002)
TX020060 (Mar. 1, 2002)
TX020061 (Mar. 1, 2002)
TX020062 (Mar. 1, 2002)
TX020063 (Mar. 1, 2002)
TX020096 (Mar. 1, 2002)

Volume VI

Oregon
OR020001 (Mar. 1, 2002)
OR020002 (Mar. 1, 2002)
OR020004 (Mar. 1, 2002)
Washington
WA020001 (Mar. 1, 2002)
WA020002 (Mar. 1, 2002)
WA020003 (Mar. 1, 2002)
WA020006 (Mar. 1, 2002)
WA020010 (Mar. 1, 2002)

Volume VII

Arizona
AZ020001 (Mar. 1, 2002)
AZ020005 (Mar. 1, 2002)
AZ020006 (Mar. 1, 2002)
California
CA020002 (Mar. 1, 2002)
CA020004 (Mar. 1, 2002)
CA020009 (Mar. 1, 2002)
CA020013 (Mar. 1, 2002)
CA020028 (Mar. 1, 2002)
CA020029 (Mar. 1, 2002)
CA020030 (Mar. 1, 2002)
CA020032 (Mar. 1, 2002)
CA020037 (Mar. 1, 2002)
Hawaii
HI020001 (Mar. 1, 2002)

General Wage Determination Publication

General wage determination 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 *http://www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic deliver of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

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 16th Day of January 2003.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 03–1407 Filed 1–23–03; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. NRTL1–2001]

TUV Product Services GmbH, Application for Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the application of TUV Product Services GmbH for expansion of its recognition as a Nationally Recognized Testing

Laboratory under 29 CFR 1910.7, and presents the Agency's preliminary finding. This preliminary finding does not constitute an interim or temporary approval of this application.

DATES: You may submit comments in response to this notice, or any request for extension of the time to comment, by (1) regular mail, (2) express or overnight delivery service, (3) hand delivery, (4) messenger service, or (5) FAX transmission (facsimile). Because of security-related problems there may be a significant delay in the receipt of comments by regular mail. Comments (or any request for extension of the time to comment) must be submitted by the following dates:

Regular mail and express delivery service: Your comments must be postmarked by February 10, 2003.

Hand delivery and messenger service: Your comments must be received in the OSHA Docket Office by February 10, 2003. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

Facsimile and electronic transmission: Your comments must be sent by February 10, 2003.

ADDRESSES: *Regular mail, express delivery, hand-delivery, and messenger service:* You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket NRTL1–2001, Room N–2625, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, DC 20210. Please contact the OSHA Docket Office at (202) 693–2350 for information about security procedures concerning the delivery of materials by express delivery, hand delivery and messenger service.

Facsimile: If your comments, including any attachments, are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648. You must include the docket number of this notice, Docket NRTL1–2001, in your comments.

Internet access to comments and submissions: OSHA will place comments and submissions in response to this notice on the OSHA Webpage *http://www.osha.gov.* Accordingly, OSHA cautions you about submitting information of a personal nature (*e.g.*, social security number, date of birth). There may be a lag time between when comments and submissions are received and when they are placed on the Webpage. Please contact the OSHA Docket Office at (202)693–2350 for information about materials not available through the OSHA Webpage and for assistance in using the Webpage to locate docket submissions. Comments and submissions will also be available for inspection and copying at the OSHA Docket Office at the address above.

Extension of Comment Period: Submit requests for extensions concerning this notice to: Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3653, 200 Constitution Avenue, NW., Washington, DC 20210. Or fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Bernard Pasquet, Office of Technical Programs and Coordination Activities, NRTL Program, Room N3653 at the address shown immediately above for the program, or phone (202) 693–2110.

SUPPLEMENTARY INFORMATION:

Notice of Application

The Occupational Safety and Health Administration (OSHA) hereby gives notice that TUV Product Services GmbH (TUVPSG) has applied for expansion of its current recognition as a Nationally Recognized Testing Laboratory (NRTL). TUVPSG's expansion request covers the use of additional test standards. OSHA's current scope of recognition for TUVPSG may be found in the following informational web page: *http://www.osha-slc.gov/dts/otpca/nrtl/tuvpsg.html.*

OSHA recognition of any NRTL signifies that the organization has met the legal requirements in § 1910.7 of title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform *independent* safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products ''properly certified'' by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications for initial recognition or for expansion or renewal of this recognition following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on an application. These notices set forth the NRTL's scope of recognition or modifications of this scope. We maintain an informational web page for each NRTL, which details its scope of recognition. These pages can be accessed from our Web site at *http://www.osha-slc.gov/dts/otpca/nrtl/index.html.*

The most recent notices published by OSHA for TUVPSG's recognition covered its initial recognition, which became effective on July 20, 2001 (66 FR 38032).

The current address of the facility (site) that OSHA recognizes for TUVPSG is: TUV Product Services GmbH, Ridlerstrasse 65, D–80339, Munich, Germany.

General Background on the Application

TUVPSG has submitted an application, dated August 1, 2002 (*see* Exhibit 7), to expand its recognition to use 46 additional test standards. The NRTL Program staff has determined that two test standards cannot be included in the expansion because they are not ''appropriate test standards,'' within the meaning of 29 CFR 1910.7(c). The staff makes similar determinations in processing expansion requests from any NRTL. Therefore, OSHA would approve 44 test standards for the expansion, which are listed below. One of the test standards requested by TUVPSG, UL 3101–2–20, is listed below using its current designation, UL 61010A–2–020.

As part of OSHA's regular audit of TUVPSG, NRTL Program assessment staff learned of TUVPSG's planned request for expansion and reviewed the NRTL's capability to test to the standards listed below. In a memo, dated July 31, 2002, (*see* Exhibit 8) the OSHA assessor recommended the expansion request.

TUVPSG seeks recognition for testing and certification of products for demonstration of conformance to the following 44 additional test standards.

UL 197 Commercial Electric Cooking Appliances
UL 250 Household Refrigerators and Freezers
UL 429 Electrically Operated Valves
UL 474 Dehumidifiers
UL 484 Room Air Conditioners
UL 499 Electric Heating Appliances
UL 749 Household Dishwashers
UL 859 Household Electric Personal Grooming Appliance
UL 873 Temperature-Indicating and -Regulating Equipment
UL 921 Commercial Electric Dishwashers
UL 923 Microwave Cooking Appliances
UL 935 Fluorescent-Lamp Ballasts
UL 982 Motor-Operated Household Food Preparing Machines
UL 998 Humidifiers
UL 1004 Electric Motors
UL 1005 Electric Flatirons
UL 1026 Electric Household Cooking and Food Serving Appliances
UL 1082 Household Electric Coffee Makers and Brewing-Type Appliances
UL 1083 Household Electric Skillets and Frying-Type Appliances

UL 1278 Movable and Wall- or Ceiling-Hung Electric Room Heaters
UL 1310 Class 2 Power Units
UL 1411 Transformers and Motor Transformers for Use In Audio-, Radio-, and Television-Type Appliances
UL 1431 Personal Hygiene and Health Care Appliances
UL 1492 Audio-Video Products and Accessories
UL 1594 Sewing and Cutting Machines
UL 1647 Motor-Operated Massage and Exercise Machines
UL 1993 Self-Ballasted Lamps and Lamp Adapters
UL 2601–1 Medical Electrical Equipment, Part 1: General Requirements for Safety
UL 60335–1 Safety of Household and Similar Electrical Appliances, Part 1; General Requirements
UL 60335–8 Household and Similar Electrical Appliances, Part 2: Particular Requirements for Shavers, Hair Clippers, and Similar Appliances
UL 60335–2–34 Household and Similar Electrical Appliances, Part 2; Particular Requirements for Motor-Compressors
UL 60730–1A Automatic Electrical Controls for Household and Similar Use; Part 1: General Requirements
UL 60730–2–7 Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Timers and Time Switches
UL 60730–2–10A Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Motor Starting Relays
UL 60730–2–11A Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Energy Regulators
UL 60730–2–12A Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Electrically Operated Door Locks
UL 60730–2–13A Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Humidity Sensing Controls
UL 60730–2–14 Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Electric Actuators
UL 60730–2–16A Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Automatic Electrical Water Level Controls
UL 61010A–2–010 Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Laboratory Equipment for the Heating of Materials
UL 61010A–2–020 Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Laboratory Centrifuges
UL 61010A–2–041 Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Autoclaves Using Steam for the Treatment of Medical Materials and for Laboratory Processes
UL 61010A–2–051 Electrical Equipment for Laboratory Use; Part 2: Particular Requirements for Laboratory Equipment for Mixing and Stirring
UL 61010A–2–061 Electrical Equipment for Laboratory Use; Part 2: Laboratory Atomic Spectrometers with Thermal Atomization and Ionization

OSHA's recognition of TUVPSG, or any NRTL, for a particular test standard is limited to equipment or materials (*i.e.*, products) for which OSHA standards require third party testing and certification before use in the workplace. Consequently, any NRTL's scope of recognition excludes any product(s) that fall within the scope of a test standard, but for which OSHA standards do not require NRTL testing and certification.

Many of the UL test standards listed above also are approved as American National Standards by the American National Standards Institute (ANSI). However, for convenience, we use the designation of the standards developing organization (*e.g.*, UL 1026) for the standard, as opposed to the ANSI designation (*e.g.*, ANSI/UL 1026). Under our procedures, any NRTL recognized for an ANSI-approved test standard may use either the latest proprietary version of the test standard or the latest ANSI version of that standard. (Contact ANSI or the ANSI Web site (*http://www.ansi.org*) and click ''NSSN'' to find out whether or not a test standard is currently ANSI-approved.)

Preliminary Finding

TUVPSG has submitted an acceptable request for expansion of its recognition. As previously mentioned, in connection with the request, OSHA has performed an on-site review (evaluation) of TUVPSG's testing capability relative to the standards listed above. The NRTL has resolved any discrepancies noted by the assessor following the review, and the assessor factored such resolution into the memo on the recommendation (*see* Exhibit 8).

Following a review of the application file, the assessor's memo, and other pertinent information, the NRTL Program staff has concluded that OSHA can grant to TUVPSG the expansion of recognition to include the test standards listed above. The staff therefore recommended to the Assistant Secretary that the application be preliminarily approved, subject to the above condition.

Based upon the recommendations of the staff, the Assistant Secretary has made a preliminary finding that TUV Product Services GmbH can meet the requirements as prescribed by 29 CFR 1910.7 for the expansion of recognition, subject to the above condition. This preliminary finding, however, does not constitute an interim or temporary approval of the applications for TUVPSG.

OSHA welcomes public comments, in sufficient detail, as to whether TUVPSG has met the requirements of 29 CFR 1910.7 for expansion of its recognition as a Nationally Recognized Testing Laboratory. Your comments should consist of pertinent written documents and exhibits. To consider a comment, OSHA must receive it at the address provided above (*see* **ADDRESSES**), no later than the last date for comments (see **DATES** above). Should you need more time to comment, OSHA must receive your written request for extension at the address provided above no later than the last date for comments. You must include your reason(s) for any request for extension. OSHA will limit any extension to 30 days, unless the requester justifies a longer period. We may deny a request for extension if it is frivolous or otherwise unwarranted. You may obtain or review copies of TUVPSG's request, the assessor's memo, and all submitted comments, as received, by contacting the Docket Office, Room N2625, Occupational Safety and Health Administration, U.S. Department of Labor, at the above address. Docket No. NRTL1–2001 contains all materials in the record concerning TUVPSG's application.

The NRTL Program staff will review all timely comments and, after resolution of issues raised by these comments, will recommend whether to grant TUVPSG's expansion request. The Assistant Secretary will make the final decision on granting the expansion, and in making this decision, may undertake other proceedings that are prescribed in Appendix A to 29 CFR 1910.7. OSHA will publish a public notice of this final decision in the **Federal Register**.

Signed in Washington, DC this 15th day of January, 2003.

John L. Henshaw,

Assistant Secretary.

[FR Doc. 03–1602 Filed 1–23–03; 8:45 am]

BILLING CODE 4510–26–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–261]

Carolina Power & Light Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–23, issued to Carolina Power & Light

Company (the licensee), for operation of the H. B. Robinson Steam Electric Plant, Unit No. 2 (HBRSEP2), located in Darlington County, South Carolina.

The proposed amendment would revise the applicable Technical specifications (TS) requirements for rod position monitoring during the current operating cycle (Cycle 22) to allow the use of an alternate method of determining rod position. This will be effective until repair of the indication system can be completed during the next shutdown of sufficient duration.

The reason for the exigency is due to the unanticipated failure of the HBRSEP2 analog rod position indicator for Control Rod H–10 in Shutdown Bank B that was declared inoperable on December 22, 2002. Additionally, there is a concern regarding excessive system wear and potential increase for a malfunction or failure.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

An evaluation of the proposed change has been performed in accordance with 10 CFR 50.91(a)(1) regarding no significant hazards considerations, using the standards in 10 CFR 50.92(c). A discussion of these standards as they relate to this amendment request follows:

1. The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The proposed change provides an alternative method for verifying the position of one control rod in a shutdown bank of rods. The proposed change meets the intent of the current TS by ensuring verification of the position of this rod once every eight hours. The proposed change only provides an alternative method of monitoring rod position and does not change the assumptions or results of any previously evaluated accident.

Therefore, operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated.

As described above, the proposed change only provides an alternative method of determining the position of one control rod in a shutdown bank of rods. No new accident initiators are introduced by the proposed alternative method of performing rod position verification. The proposed change does not affect the reactor protection system or the reactor control system. Hence, no new failure modes are created that would cause a new or different kind of accident from any accident previously evaluated.

Therefore, operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any previously evaluated.

3. The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety.

The Bases of TS 3.1.7 states that the operability of the rod position indicators is required to determine control rod positions and thereby ensure compliance with the control rod alignment and insertion limits. The proposed change does not alter the requirement to determine rod position, but provides an alternative method for determining the position of the affected rod. As a result, the initial conditions of the accident analyses are preserved, and the consequences of previously analyzed accidents are unaffected.

Therefore, operation of the facility in accordance with the proposed amendment would not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 14 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 14-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 14-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike, Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 24, 2003, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714,[1] which is available at the Commission's PDR, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike, Rockville, Maryland, and available electronically on the Internet at the NRC Web site *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the

[1] The most recent version of Title 10 of the Code of Federal Regulations, published January 1, 2002, inadvertently omitted the last sentence of 10 CFR 2.714(d) and subparagraphs (d)(1) and (2), regarding petitions to intervene and contentions. For the complete, corrected text of 10 CFR 2.714(d), please see 67 FR 20884 (April 20, 2002).

Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's PDR, located at One White Flint North, Public File Area O1 F21,11555 Rockville Pike, Rockville, Maryland, by the above date. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that petitions for leave to intervene and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and because of continuing disruptions in delivery of mail to United States Government offices, it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by e-mail to OGCMailCenter@nrc.gov. A copy of the request for hearing and petition for leave to intervene should also be sent to William D. Johnson, Vice President and Corporate Secretary, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 16, 2003, which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike, Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC web site *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, MD, this 17th day of January 2003.

For the Nuclear Regulatory Commission.

Chandu P. Patel,

Project Manager, Section 2, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–1636 Filed 1–23–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346]

FirstEnergy Nuclear Operating Co; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of FirstEnergy Nuclear Operating Company (the licensee) to withdraw its March 30, 2001, application for proposed amendment to Facility Operating License No. NPF–3 for the Davis-Besse Nuclear Power Station, Unit No. 1, located in Ottawa County, Ohio.

The proposed amendment would have revised the Technical Specifications regarding surveillance

testing of the watertight enclosure for Decay Heat Removal System valves DH–11 and DH–12 to decrease the frequency of functional testing.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on May 30, 2001 (66 FR 29355). However, by letter dated December 20, 2002, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated March 30, 2001, and the licensee's letter dated December 20, 2002, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike, Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams/html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, MD, this 17th day of January 2003.

For the Nuclear Regulatory Commission.

Jon Hopkins,

Senior Project Manager, Section 2, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–1635 Filed 1–23–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–26–ISFSI; ASLBP No. 02–801–01–ISFSI]

Atomic Safety and Licensing Board; Pacific Gas and Electric Co.; (Diablo Canyon Power Plant Independent Spent Fuel Storage Installation); Notice (Notice of Opportunity To Make Oral or Written Limited Appearance Statements)

January 16, 2003.

Before Administrative Judges: G. Paul Bollwerk, III, Chairman, Dr. Jerry R. Kline, Dr. Peter S. Lam.

The Atomic Safety and Licensing Board hereby gives notice that, in accordance with 10 CFR 2.715(a), the Board will conduct sessions to provide the public with an opportunity to make oral limited appearance statements in connection with this proceeding regarding the December 21, 2001 application of Pacific Gas and Electric Company (PG&E) under 10 CFR part 72 for permission to construct and operate an independent spent fuel storage installation (ISFSI) at its Diablo Canyon Power Plant (DCPP) site near San Luis Obispo, California.

A. Date, Time, and Location of Oral Limited Appearance Statement Sessions

These sessions will be on the following dates at the specified location and times:

1. *Date:* Sunday, March 23, 2003.

Time: Afternoon Session (if there is sufficient interest)—3 p.m. to 7 p.m. Pacific Standard Time (PST).

Location: Embassy Suites Hotel, San Luis Obispo Room, 333 Madonna Rd., San Luis Obispo, California 93405.

2. *Date:* Monday, March 24, 2003.

Times: Morning Session (if there is sufficient interest)—10 a.m. to Noon PST, Afternoon Session—1:30 p.m. to 4:30 p.m. PST, Evening Session—6:30 p.m. to 9:30 p.m. PST.

Location: Same as Session 1 above.

B. Participation Guidelines for Oral Limited Appearance Statements

Any person not a party, or the representative of a party, to the proceeding will be permitted to make an oral statement setting forth his or her position on matters of concern relating to this proceeding. Although these statements do not constitute testimony or evidence, they nonetheless may help the Board and/or the parties in their consideration of the issues in this proceeding.

Oral limited appearance statements will be entertained during the hours specified above, or such lesser time as may be necessary to accommodate the speakers who are present. In this regard, if all scheduled and unscheduled speakers present at a session have made a presentation, the Licensing Board reserves the right to terminate the session before the ending time listed above. The Licensing Board also reserves the right to cancel the Sunday afternoon and/or Monday morning sessions scheduled above if there has not been a sufficient showing of public interest as reflected by the number of preregistered speakers.

The time allotted for each statement normally will be no more than five minutes, but may be further limited depending on the number of written requests to make an oral statement that are submitted in accordance with section C below and/or the number of persons present at the designated times. In addition, although an individual may request an opportunity to speak at more than one session, the Licensing Board reserves the right to defer an additional presentation by the same individual until after it has heard from speakers who have not had an opportunity to make an initial presentation.

C. Submitting a Request To Make an Oral Limited Appearance Statement

Persons wishing to make an oral statement who have submitted a timely written request to do so will be given priority over those who have not filed such a request. To be considered timely, a written request to make an oral statement must be mailed, faxed, or sent by e-mail so as to be received by close of business (4:30 p.m. EST) on *Friday, March 14, 2003.* The request must specify the date (March 23 or March 24) and the session on that day (morning, afternoon or evening) during which the requester wishes to make an oral statement. Based on its review of the requests received by March 14, 2003, the Licensing Board may decide that the Sunday afternoon and/or Monday morning sessions will not be held due to lack of adequate interest in those sessions.

Written requests to make an oral statement should be submitted to:

Mail: Office of the Secretary, Rulemakings and Adjudications Staff, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Fax: (301) 415–1101 (verification (301) 415–1966).

E-mail: hearingdocket@nrc.gov.

In addition, using the same method of service, a copy of the written request to make an oral statement should be sent to the Chairman of this Licensing Board as follows:

Mail: Administrative Judge G. Paul Bollwerk, III, Atomic Safety and Licensing Board Panel, Mail Stop T–3F23, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Fax: (301) 415–5599 (verification (301) 415–7550).

E-mail: pah@nrc.gov and *gpb@nrc.gov.*

D. Submitting Written Limited Appearance Statements

As the Board noted previously in its December 27, 2002 notice of hearing (68 FR 391 (Jan. 3, 2003)), a written limited appearance statement can be submitted at any time. Such statements should be sent to the Office of the Secretary using

the methods prescribed above, with a copy to the Licensing Board Chairman.

E. Availability of Documentary Information Regarding the Proceeding

Documents relating to this proceeding are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, or electronically from the publicly available records component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* (the Public Electronic Reading Room). Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

It is so *ordered.*

Dated: January 16, 2003.

For the Atomic Safety and Licensing Board.*

G. Paul Bollwerk, III,

Administrative Judge.

[FR Doc. 03–1538 Filed 1–23–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8905]

Notice of Receipt of Mill Demolition Plan for Rio Algom Mining LLC's Ambrosia Lake Uranium Mill Facility, New Mexico, and Opportunity to Provide Comments and to Request a Hearing

I. Introduction

The Nuclear Regulatory Commission (NRC) has received, by letter dated December 10, 2002, a proposed mill demolition plan for the removal of the mill located at Rio Algom Mining Limited Liability Corporation's uranium mill facility at Ambrosia Lake, New Mexico. In accordance with License Condition #29 of NRC Source Materials License, SUA–1473, the mill demolition plan describes the demolition of the structural features associated with the Ambrosia Lake uranium mill facility. The plan addresses the removal of surface structures in preparation for subsequent implementation of the surface reclamation release phase of the overall site decommission process.

II. Opportunity to Provide Comments

The NRC is providing notice to individuals in the vicinity of the facility that the NRC is in receipt of this request, and will accept comments concerning this action within 30 days of the publication of this notice in the **Federal Register**. The comments may be provided to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room T–6 D59, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852, from 7:30 a.m. until 4:15 p.m. on Federal workdays.

III. Opportunity to Request a Hearing

The NRC hereby provides notice that this is a proceeding on an application for an amendment of a license falling within the scope of subpart L, ''Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings'' of NRC's rules and practice for domestic licensing proceedings in 10 CFR part 2. Whether or not a person has or intends to provide comments as set out in Section II above, pursuant to § 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing in accordance with § 2.1205(d). A request for a hearing must be filed within 30 days of the publication of this **Federal Register** notice.

The request for a hearing must be filed with the Office of the Secretary, either:

(1) By delivery to the Rulemaking and Adjudications Staff of the Office of the Secretary of the Commission at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(2) By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications Staff. Because of continuing disruptions in the delivery of mail to United States Government offices, it is requested that requests for hearing also be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101, or by e-mail to *hearingdocket@nrc.gov.*

In accordance with 10 CFR 2.1205(f), each request for a hearing must also be served, by delivering it personally or by mail, to:

(1) The applicant, Rio Algom Mining Limited Liability Corporation, 6305 Waterford Blvd., Suite 400, Oklahoma City, OK 73118, Attention: W. Paul Goranson; and

(2) The NRC staff, by delivery to the General Counsel, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or by mail addressed to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Because of continuing disruptions in the delivery of mail to United States Government offices, it is requested that requests for hearing also be transmitted to the Office of the General Counsel, either by means of facsimile transmission to 301–415–3725, or by email to *OGCMailCenter@nrc.gov.*

In addition to meeting other applicable requirements of 10 CFR part 2 of the NRC's regulations, a request for a hearing filed by a person other than an applicant must describe in detail:

(1) The interest of the requestor;

(2) How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(h);

(3) The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and

(4) The circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(d).

IV. Further Information

The application for the license amendment and proposed decommissioning and reclamation plan are available for inspection at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html* [ADAMS Accession Number ML030070154]. Documents may also be examined and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. Any questions with respect to this action should be referred to Jill Caverly, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T8–A33, Washington, DC 20555–0001. Telephone: (301) 415–6699, Fax: (301) 415–5390.

Dated at Rockville, Maryland, this _16th day of January 2003.

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* Copies of this notice were sent this date by Internet e-mail transmission to counsel for (1) applicant PG&E; (2) petitioners San Luis Obispo Mother For Peace, *et al.;* (3) San Luis Obispo County, California, the Port San Luis Harbor District, the California Energy Commission, the Avila Beach Community Services District, and the Diablo Canyon Independent Safety Committee; and (4) the NRC staff.

For the U.S. Nuclear Regulatory Commission:

Daniel M. Gillen

Chief, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 03–1638 Filed 1–23–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–438 and 50–439]

Tennessee Valley Authority; Bellefonte Nuclear Plant, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an extension of the Construction Permit No. CPPR–122 for Bellefonte Nuclear Plant (BLN), Unit 1, and CPPR–123 for BLN, Unit 2, issued to the Tennessee Valley Authority (TVA) (permittee). The facility is located about 6 miles east-northeast of Scottsboro, Alabama, on the west shore of the Guntersville Reservoir at Tennessee River Mile 392, in Jackson County, Alabama. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of Proposed Action

The proposed action would extend the construction permit expiration date for BLN, Unit 1, from October 1, 2001, to October 1, 2011, and the construction permit expiration date for BLN, Unit 2, from October 1, 2004, to October 1, 2014. The proposed action is in response to TVA's request, dated July 11, 2001.

The Need for the Proposed Action

The proposed action is needed because construction of BLN, Units 1 and 2, is not yet completed. TVA requested the extension to allow it to maintain the choice of a full range of competitive energy sources. The request was made because of the increase in the electrical demand in the TVA region.

Environmental Impacts of the Proposed Action

The environmental impacts associated with the construction of the facility have been previously discussed and evaluated in the Final Environmental Statement (FES), June 1974, prepared as part of the NRC staff's review of the construction permit application. Because of the passage of time from the issuance of the FES, the staff requested additional information in a June 5, 2002, letter to TVA to determine if the conclusions reached in the June 1974 FES remain valid. TVA responded to these questions in a letter dated August 26, 2002.

In its August 26, 2002, response, TVA addressed the impact of resumption of construction in the following areas: Archaeological sites and historic properties, disturbance of land, socioeconomic impacts, additional cumulative impacts from other projects in the area, and threatened and endangered species. Highlights of TVA's response follow. TVA stated that no additional archaeological sites have been identified in areas that might be affected by the resumption of construction activities. No future disturbance is currently contemplated on or adjacent to known archaeological sites. The NRC staff asked TVA how they responded to the recommendation by the Alabama Historical Commission on adaptive re-use of the 1845 Tavern and Inn. TVA responded that the building has been removed since 1974 when it was determined that site was eligible for placement on the National Register of Historic Places. The 1845 Tavern and Inn is not on TVA property, and the buildings were removed by the owners. Before construction of the existing site facilities, the Alabama State Historic Preservation Office approved the design and indicated that no mitigation would be required.

Regarding disturbance of land, TVA stated that almost all of the construction required for completion of the BLN site as a two-unit nuclear plant has been started and very few facilities remain that would require new land disturbance. TVA stated that the remaining construction that would require new land disturbance are as follows:

1. If construction resumes, it is planned to eventually move (re-route) the first half mile of the south entrance road such that it would still join Jackson County Highway 33, but to an intersection which is about 1200 feet east of the current connection point. The site has completed an environmental assessment for this change which would improve traffic visibility and thereby increase commuter safety. Some new ground would be disturbed for this road, but there are no associated significant environmental impacts.

2. If construction resumes, some new backfill borrow pits may be required to obtain clay. These would likely be made in undisturbed ground east of the main site power plant buildings. The topsoil would be removed temporarily and replaced to restore the sites after clay removal. Tree cover would be removed in this process.

3. Meteorological monitoring requirements have changed, which might necessitate construction of a new environmental data station. This new facility could possibly be sited on undisturbed soil.

4. Construction of the startup and recirculation equipment building for Unit 2 has not been initiated; however, the site for this building is disturbed ground very close to the south side of the Unit 2 auxiliary building. Other potential construction activities on disturbed ground include increasing the size of the construction and administration building (CAB); additional fire protection tanks by the CAB; additional waste tanks adjacent to the Unit 1 reactor building; and completion of the auxiliary feedwater pipe trench near the Unit 2 reactor building. The power stores building may be enlarged, and new plant security requirements may necessitate changes to the gatehouse.

The FES evaluated the terrestrial and aquatic impacts due to construction of the BLN, Units 1 and 2. Included in these impacts were development of access corridors (roads), and clearing and excavation for all construction. The FES requires a construction monitoring program to monitor the effect of these activities on the environment. If construction is resumed, these activities will be monitored by the construction monitoring program and, therefore, the conclusions of the FES regarding potential land disturbance remain valid.

The socioeconomic impacts have changed since the 1974 FES was issued. In 1970, the population in the surrounding area was 39,202 and in 2000, the population was 59,926. The 1974 FES estimated a peak workforce of 2,300 people. The actual workforce peaked at 4,600 people prior to construction being suspended in 1988. TVA estimates that the workforce required to complete construction will peak at 4,600. The staff questioned if these changes to the demographics of the region may lead to significant socioeconomic impacts different from those previously evaluated in the FES. Examples of these impacts are demands on the local schools, hospitals, public facilities, utilities (*e.g.*, water use), transportation infrastructure, and construction worker shortages. TVA responded that:

The FES addressed both temporary impacts to community facilities and services which would occur during the construction period and those which would occur from the permanent workforce. Significant impacts were not expected in either case, but the FES concluded that facilities and services such as schools would unavoidably be stressed by construction and operation of BLN. Consequently, TVA committed to monitoring the situation and to working with local and state officials to mitigate any unacceptable adverse conditions which might result.

The currently larger projected construction workforce will likely result in greater

socioeconomic impacts that [sic] those projected in the FES. Two more recent Environmental Impact Statements analyze potential impacts at higher levels than those in the FES. The first of these analyzed potential impacts of converting and operating the Bellefonte site as a fossil-fueled power plant (Final Environmental Impact Statement for the Bellefonte Conversion Project, Tennessee Valley Authority, October 1997). The second analyzed the impacts associated with the production of tritium at various TVA nuclear sites, including the BLN site (Final Environmental Impact Statement for the Production of Tritium in a Commercial Light Water Reactor, U.S. Department of Energy, DOE/EIS—0288, March 1999). Impacts of a peak construction employment level of 4,500, almost the same as now projected, were analyzed in the latter report. Based on these analyses, we would anticipate that about 1,500 workers would move into the area at peak construction (at sometime during the fourth year of construction). Of these, about 1,100 are likely to move to Jackson County, and the remainder to surrounding counties. This number of movers would result directly in a population increase in Jackson County of about 3,000 persons or less at peak construction. The maximum impact on Jackson County schools is estimated to be somewhat less than 1,000 additional students, roughly a ten percent increase. This level of impact, however, would be only for a short time with lesser impacts leading up to this peak and following it. Impacts on other public services, such as hospitals, transportation, and utilities are discussed in more detail in the documents referenced above. They would be significant at or near peak, but the higher levels would have a relatively short duration. Possible impacts on construction worker shortages would depend on the magnitude of other construction projects in the larger area around the BLN site. The labor market area for construction workers is much larger than for most other types of work, and construction workers typically move around within large areas thereby decreasing the likelihood of significant problems for other construction projects. All of these impacts would occur gradually, as the construction workforce builds up to its peak during the fourth year. If construction resumes, TVA will work with state and local officials and civic groups mitigate possible adverse socioeconomic impacts caused by activities undertaken to complete construction of BLN or to operate the plant after its completion.

Based on TVA's response, and the recent environmental impact statements cited above, the NRC staff concludes that, while the impacts will be larger if construction resumes, the mitigative actions will be commensurate with the larger impacts and, therefore, the conclusions reached in the FES remain valid.

The staff questioned if there were any projects or activities occurring or planned for the area that may lead to additional cumulative impacts to the surrounding population or to the natural environment. TVA responded that, in general, this growth has consisted of numerous small-to-medium size changes rather than one or a few very large events, except for the starting and stopping of TVA nuclear construction. The projected construction employment would be a major addition to the economy of Jackson County. However, many of the workers would live elsewhere in the labor market area, including some who would temporarily relocate. Within the construction labor market area, the employment increase at peak construction would be about 46 to 50 percent of the recent annual increase in employment. During most of the construction period, however, the level would be smaller. In contrast to construction at or near peak, operating employment levels would be small compared to the normal growth of the area. In the 1974 FES, TVA committed to work with state and local officials and civic groups throughout the construction and operation of the BLN site to mitigate the possible socioeconomic impacts. Based on the above commitment contained in the FES, the conclusion of the FES remains valid.

Regarding threatened and endangered species, the NRC staff, in its June 5, 2002, letter, asked if any biota has been added to or removed from the list of threatened or endangered species for the BLN site environs (including transmission line rights-of-way) based on field studies or revisions to the threatened and endangered species list since the 1974 FES. TVA responded that no species indigenous to the BLN site have been added to the federal or state lists of threatened or endangered species since the original FES. The Peregrine Falcon has been delisted. Two species, the Bald Eagle and Indiana Bat, are currently listed as threatened or endangered for Jackson County, Alabama, by the Environmental Protection Agency. Osprey, Pandion haliaetus, is not federally listed, but is listed as threatened by the State of Alabama. Population levels of osprey have been increasing on Guntersville Lake, and several nests have been observed in the vicinity of Coon and Crow Creeks. This species would use shoreline habitats fronting the BLN site for foraging. The current list of federally threatened or endangered species for Jackson County, Alabama, contains several species which were not identified or discussed in the original FES for BLN. However, none of these except the Gray Bat are known to occur at or adjacent to the BLN site, including transmission line rights-of-way, and none of these were added based on field studies at the BLN site. Gray bats forage in the sloughs and main channel of the Tennessee River. However, because of the nature of the activities undertaken at the plant and the distance of these plant activities from the foraging area, Gray Bats would not be adversely impacted by the proposed actions.

The staff also questioned if there were any known potential adverse impacts to any listed or candidate species that might result from the resumption of construction at BLN. TVA responded that resumption of construction activities at BLN would not be expected to cause adverse impacts to any Federal or State-listed or candidate species or their habitats. This is primarily because almost all ground or river disturbance construction activities have long since been completed. Therefore, resumption of construction is unlikely to have any significant effect on threatened or endangered species at BLN.

Since almost all of the construction required for completion of BLN as a two-unit nuclear plant has already been, at least, started, very few facilities remain that would require new land disturbance; therefore, most of the construction impacts discussed in the FES have already occurred. This action would extend the period of construction as described in the FES. It does not invalidate any of the conclusions reached in the 1974 FES. The proposed extension will not allow any work to be performed that is not already allowed by the existing construction permit. The extension will grant TVA more time to complete construction in accordance with the previously approved construction permit. In addition, it is the policy of the Commission that a licensee will notify the NRC at least 120 days before plant construction is expected to resume.

Based on the foregoing, the NRC staff has concluded that the proposed action would have no significant environmental impact. Because this action would only extend the period of construction activities described in the FES, it does not involve any different impacts or a significant change to those impacts described and analyzed in the FES. Consequently, an environmental impact statement addressing the proposed action is not required.

Environmental Impacts of the Alternatives to the Proposed Action

A possible alternative to the proposed action would be to deny the request. This would result in expiration of the construction permit for BLN, Units 1 and 2. This option would require submittal of another application for

construction in order to allow the permittee to complete construction of the facility with no significant environmental benefit. The environmental impacts of the proposed action and alternative action are similar.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the FES for BLN, Units 1 and 2.

Agencies and Persons Contacted

In accordance with its stated policy, the staff consulted with the Alabama State Official, Mr. David Walter of the Alabama Office of Radiation Control, regarding the environmental impact of the proposed action. The State official had no comments.

For further details with respect to this action, see the licensee's request for extension dated July 11, 2001, and its response to the staff's request for additional information dated August 26, 2002.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that this action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for this action. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area 01–F21, 11555 Rockville Pike, Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 16th day of January 2003.

For the Nuclear Regulatory Commission.

Allen G. Howe,

Chief, Section 2, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–1637 Filed 1–23–03; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Notice of Meeting

AGENCY: Postal Service.

ACTION: Notice of meeting.

SUMMARY: The Postal Service will hold the first meeting of a Consensus Committee to develop recommendations for revision of USPS STD 4B, which governs the design of apartment house mailboxes. The committee will develop and adopt its recommendations through a consensus process. The committee will consist of persons who represent the interests affected by the proposed rule, including apartment house type mailbox manufacturers, mailbox distributors, mailbox installers and servicers, postal customers, and apartment house builders, owners and managers.

Meeting Dates: The first committee meeting is tentatively scheduled to begin at 9 a.m. on February 5th and continue into February 6th, 2003.

Meeting Place: Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024..

FOR FURTHER INFORMATION CONTACT: Jeffery W. Lewis, (202) 268–4757.

SUPPLEMENTARY INFORMATION: Mail comments and all other communications regarding the committee to Jeffery W. Lewis, U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., Room 7142, Washington, DC 20260. Committee documents will be available for public inspection and copying between 9 a.m. and 4 p.m. weekdays at the address above. Persons intending to attend the February 5th and 6th, 2003, meeting should send a fax to Monica J. Skinner at 202–268–5418 as soon as possible with the person's name and organizational affiliation, if any. For additional information regarding the USPS STD 7A Consensus Committee, *see* **Federal Register** Vol. 68, No. 3, p. 530 (January 6, 2003).

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 03–1582 Filed 1–23–03; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration on the New York Stock Exchange, Inc. (Cornerstone Strategic Value Fund, Inc., Common Stock, $.01 Par Value) File No. 1–09555

January 17, 2003.

Cornerstone Strategic Value fund, Inc., a Maryland corporation (''Issuer''), has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities and Exchange Act of 1934 (''Act'') [1] and rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock, $.01 par value (''Security''), from listing and registration on the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'').

The Board of Directors of the Issuer (''Board'') approved a resolution on December 2, 2002 to withdraw the Issuer's Security from listing on the NYSE. In making its decision to withdraw the Security from the Exchange, the Board determined that it was in the Issuer's best interest to delist from the NYSE and list on the American Stock Exchange LLC (''Amex'') due to the continued decline in the level of net assets which would affect the Issuer's ability to remain listed on the NYSE. The Issuer anticipates that it will begin trading on the Amex once the Issuer is delisted from the NYSE.

The Issuer stated in its application that it has complied with the NYSE's rules governing an issuer's voluntary withdrawal of a security from listing and registration. The Issuer's application relates solely to the Security's withdrawal from listing on the NYSE and from registration under Section 12(b) of the Act [3] and shall not affect its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before February 10, 2003, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 03–1605 Filed 1–23–03; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration on the New York Stock Exchange, Inc. (Cornerstone Total Return Fund, Inc., Common Stock, $.01 Par Value) File No. 1–31582

January 17, 2003.

Cornerstone Total Return Fund, Inc., a New York corporation (''Issuer''), has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock $.01 par value (''Security''), from listing and registration on the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'').

The Board of Directors of the Issuer (''Board'') approved a resolution on December 2, 2002 to withdraw the Issuer's Security from listing on the NYSE. In making its decision to withdraw the Security from the Exchange, the Board determined that it was in the Issuer's best interest to delist form the NYSE and list on the American Stock Exchange LLC due to the continued decline in the level of net assets which would affect the Issuer's ability to remain listed on the NYSE. The Company anticipates that it will begin trading on the Amex once the Issuer is delisted from the NYSE.

The Issuer stated in its application that it has complied with the NYSE's rules governing an issuer's voluntary withdrawal of a security from listing and registration. The Issuer's application relates solely to the Security's withdrawal from listing on the NYSE and from registration under Section 12(b) of the Act[3] and shall not affect its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before February 10, 2003, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the NYSE and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 03–1604 Filed 1–23–03; 8:45 am]

BILLING CODE 8010–01–M

[5] 17 CFR 200.30–3(a)(1).

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration on the New York Stock Exchange, Inc. (Progressive Return Fund, Inc., Common Stock, $.001 Par Value) File No. 1–10341

January 17, 2003.

Progressive Return Fund, Inc., a Maryland corporation (''Issuer''), has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock, $.001 par value (''Security''), from listing and registration on the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'').

The Board of Directors of the Issuer (''Board'') approved a resolution on December 2, 2002 to withdraw the Issuer's Security from listing on the NYSE. In making its decision to withdraw the Security from the Exchange, the Board determined that it was in the Issuer's best interest to delist from the NYSE and list on the American Stock Exchange LLC (''Amex'') due to the continued decline in the level of net assets which would affect the Issuer's ability to remain listed on the NYSE. The Issuer anticipates that it will begin trading on the Amex once the Issuer is delisted from the NYSE.

The Issuer stated in its application that it has complied with the NYSE's rules governing an issuer's voluntary withdrawal of a security from listing and registration. The Issuer's application relates solely to the Security's withdrawal from listing on the NYSE and from registration under Section 12(b) of the Act[3] and shall not affect its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before February 10, 2003, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the NYSE and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 03–1603 Filed 1–23–03; 8:45 am]

BILLING CODE 8010–01–M

[5] 15 CFR 200.30–3(a)(1).

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

[5] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47202; File No. SR–MSRB–2002–14]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of Proposed Rule Change Relating to Market Emergencies

January 16, 2003.

Pursuant to section 19(b)(1) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') and Rule 19b–4 thereunder,[1] notice is hereby given that on December 11, 2002, the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change (File No. SR–MSRB–2002–14) (the ''proposed rule change'') described in Items I, II, and III below, which Items have been prepared by the MSRB. The SEC is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4 thereunder.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB is filing a proposed rule change concerning market emergencies consisting of an Interpretation of its Rule G–17, on conduct of municipal securities activities and an amendment to its Rule A–4, on meetings of the Board.

The text of the proposed rule change follows. Italics indicate proposed additions.

Rule G–17. Conduct of Municipal Securities Activities

Interpretation of Rule G–17—Effecting Transactions During Market Emergency

It is inconsistent with the principles of fair dealing embodied in Rule G–17 for a broker, dealer or municipal securities dealer to effect transactions in municipal securities during a market emergency. For purposes of this interpretation, a market emergency is any situation causing a substantial failure in any of the systems necessary for clearance, settlement, confirmation, payment, or delivery of transactions in municipal securities or in other systems necessary for the prompt execution and consummation of municipal securities transactions or the fair and accurate pricing of municipal securities. In determining whether such a market emergency exists, a broker, dealer or municipal securities dealer shall rely upon the issuance of official announcements by the MSRB concerning market emergencies, which shall be issued after consultation with the Securities and Exchange Commission. Official announcements by the MSRB on market emergencies will be communicated to brokers, dealers and municipal securities dealers through news outlets commonly used in the municipal securities industry, by posting on the MSRB's World Wide Web site at www.msrb.org, and by transmittal of the announcement to the electronic mail addresses provided to the MSRB by brokers, dealers and municipal securities dealers under Rule G–40. Such official announcements will include information on the nature of the market emergency and affected systems, the nature and scope of transactions affected, and the status of the market emergency and its expected duration, if that is known.

Rule A–4. Meetings of the Board

(a) through (d) No Change.

(e) Special Meetings on Market Emergencies. Notwithstanding anything in these rules to the contrary, the following procedures govern special meetings to act on market emergencies: (i) notice of special telephone conference call meeting on a market emergency shall be sent to all Board members by the Executive Director, or in the absence of the Executive Director, by his or her designee: (A) as soon as possible after credible information is received suggesting the existence of a market emergency, and (B) during the existence of a declared market emergency, within 24 hours of a request by any Board member; (ii) notice of a special meeting on a market emergency, including a description of the proposed Board action and instructions for joining the conference call, shall be given by telephone and by e-mail to all Board members; (iii) the Executive Director, or his or her designee, shall consult with the Commission on the emergency situation prior to a special meeting on a market emergency, if possible; (iv) the quorum requirement for a special meeting on a market emergency shall be five members and there shall be no requirement that at least one public representative, one broker-dealer representative and one bank representative be present; and (v) any action taken at such a meeting shall be by a majority vote of Board members attending the meeting and shall be limited to declaring a market emergency or ending a declared market emergency. For purposes of this paragraph (e), the meaning of the term ''market emergency'' shall be as defined in ''Notice of Interpretation of Rule G–17—Effecting Transactions During Market Emergency,'' dated_____.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the SEC, the MSRB 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 MSRB has prepared summaries, set forth in Section 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

After the events of September 11, 2001, staff of the Commission and the MSRB met to discuss how the municipal securities market functioned in the aftermath of the attacks on the World Trade Center. On September 11, and in the days following, MSRB monitored the municipal securities market through its contacts with dealers, clearing corporations and information providers.

Although the effect on lower Manhattan was severe, because the municipal securities market is decentralized, the municipal securities market as a whole was not affected to the same degree as securities exchanges physically located near the disaster. On September 11, some trading in municipal securities occurred, albeit a very limited amount. Based on transactions reported to the MSRB's Transaction Reporting System, trade volume reached 8,244 trades by September 13 and 17,941 trades by September 17. On September 19 and 20 transaction volume reached 23,996 and 26,155 trades respectively. Prior to September 11, in a typical day, 27,000 transactions were processed.

Aside from dealer operations in Manhattan, in general, the infrastructure and systems necessary for processing transactions in the municipal securities market functioned in the days after September 11. Clearance and settlement systems for municipal securities transactions provided by Depository Trust and Clearing Corporation (DTCC) remained operational, although telecommunications problems in Manhattan did affect the ability of dealers in that area to exchange data with DTCC. The problems with clearing bank functions that disrupted the government securities market did not substantially affect the municipal securities market.

Despite the resilience of municipal securities market systems and infrastructure on September 11, there remains a concern about what might have happened if the situation had been different. Had systems or infrastructure critical to the municipal securities market been disabled by the disaster, no legal or regulatory mechanism existed to temporarily halt trading. For example, any problems with central clearance and settlement systems are of an immediate concern, since the accumulation of unsettled trades, particularly in a volatile or chaotic market, presents risks to all segments of the market. Commission staff accordingly have asked MSRB to consider rulemaking to provide a procedure for a trading halt should a market emergency disable critical market systems or infrastructure in the future.

The proposed rule change would provide such a procedure. Should a similar situation occur in the future, MSRB would review conditions in the

market through its contacts with dealers, clearing agencies and vendors of critical services to the market just as it did after September 11. The proposed rule change, however, includes changes to MSRB's administrative procedures in Rule A–4 allowing special MSRB telephone conference call Board meetings on market emergencies to occur without the normal notice requirement of seven days or the normal quorum requirement of two-thirds of the Board's members. The proposed rule change also includes a format interpretation of Rule G–17, on fair practice, that would prohibit dealers from trading for the duration of a market emergency declared by the MSRB. These proposed rule changes thus provide a procedure for instituting a trading halt should a market emergency necessitate one in the future.

The proposed rule change specifically identifies the channels by which MSRB would make information known to municipal securities dealers in the event of a market emergency. It notes that this will be done through new outlets commonly used in the municipal securities industry, postings on the MSRB's Web site and by transmitting announcements to the electronic mail addresses provided to the MSRB by dealers under Rule G–40, on electronic mail contacts. Having an announced, written procedure for dealer notification would add a level of preparedness if a market emergency actually occurs. Just as important, it provides dealers with clear direction on where to look if the situation is uncertain and questions exist about whether an emergency has been declared. This also will help dealers determine if any other emergency rulemaking is in effect. After September 11 there was some confusion among municipal securities dealers about whether the regular-way settlement cycle for municipal securities had been changed to T+5 from the T+3 cycle mandated under MSRB Rules G–12(b)(ii) and G–15(b)(ii). This apparently was the result of announcements made concerning transactions in government bonds. In monitoring clearance and settlement data after September 11, the MSRB observed that some dealers were, as a practice, submitting all of their regular-way trades with a T+5 settlement date. Among other problems, this caused trade-matching failures in the central comparison system for inter-dealer transactions. The notification procedure for market emergency declaration will help direct the attention of dealers in municipal securities to the MSRB for announcements on possible rule changes in the wake of an emergency and thus should help to avoid similar confusion in the future.[2]

The proposed rule change's interpretation of Rule G–17 follows a principle of securities law that a dealer must not ''accept or execute any order for the purchase or sale of securities or induce or attempt to induce such purchase or sale if the dealer does not have the personnel and facilities to enable prompt execution and consummation of the transactions.''[3] The MSRB believes that, where a substantial failure has occurred in the systems necessary for clearance, settlement, confirmation, payment or delivery of transactions in municipal securities, or in other systems necessary for the prompt execution and consummation of municipal securities transactions or the fair and accurate pricing of municipal securities, it may become necessary, for the overall protection of market participants, to halt trading by all dealers.[4] Clearance and settlement systems are a particular concern because of counter-party risk that escalates when unsettled transactions grow during volatile or chaotic markets. Other situations possibly warranting a temporary halt in trading might include a massive failure of telecommunication systems, or the corruption of essential data used by the municipal securities industry (for example, through a computer virus).

Interpretation of Rule G–17

The proposed Interpretation of Rule G–17 has the following elements:

- It is a violation of Rule G–17 for a dealer to continue to effect transactions in municipal securities during an MSRB-declared ''market emergency.''
- A ''market emergency'' for this purpose is defined as ''a situation causing substantial failure in any of the systems necessary for clearance, settlement, confirmation, payment or delivery of transactions in municipal securities, or in other systems necessary for the prompt execution and consummation of municipal securities transactions or the fair and accurate pricing of municipal securities.''
- Prior to acting on a market emergency, MSRB will consult with the SEC.
- Official announcements by the MSRB on market emergencies will be communicated to dealers through news outlets commonly used in the municipal securities industry, by posting on the MSRB's World Wide Web site at *http://www.msrb.org,* and by transmittal of the announcement to the electronic mail addresses provided to the MSRB by dealers under Rule G–40.

Amendment to Rule A–4

Prior to making any decision on a specific market emergency, the MSRB will hold a special Board meeting to share information and discuss the situation. The MSRB's current procedure for holding special Board meetings is contained in Rule A–4. Among other provisions, the rule states that the Secretary of the Board will call special meetings at the request of the Chairman or at the written request of three or more members. Seven days written notice, signed by the Secretary of the Board (or three days notice if given or sent by telephone, e-mail or personal delivery), is required for special meetings. The quorum for any Board meeting is two-thirds of the Board (normally ten members), with at least one securities firm representative, one bank dealer representative and one public member. Formal action requires an affirmative vote of the majority of the Board (normally eight members).

During a time of crisis, market participants would want to know fairly quickly whether trading is to be halted. The existing seven-day and three-day notice requirements for special Board meetings thus seem impractical. Moreover, establishing communication with at least ten Board members and securing eight affirmative votes also might present a problem, particularly if the emergency in question affects the infrastructure of one or more major financial centers and members cannot be reached. The proposed rule change would streamline the process specifically for market emergency meetings. The proposed amendments to Rule A–4 provides the following procedure:

- The Executive Director, or his or her designee, will schedule a special telephone conference call meeting on the possible declaration of a market

[2] The proposed rule change addresses only the procedure for announcing trading halts. Should changes in existing MSRB rules be necessary during an emergency, these could be adopted by the MSRB and approved summarily by the SEC. Section 19(b)(3)(B) of the Exchange Act grants the SEC authority to approve proposed rule changes summarily when ''it appears to the Commission that such action is necessary for the protection of investors, the maintenance of fair and orderly markets, or the safeguarding of securities or funds.''

[3] *See, e.g.,* Release No. 8363 (July 29, 1968), 33 FR 11150 (August 7, 1968).

[4] The scope of the proposed rule change does not include the issuance of ''regulatory halts'' similar to those issued by exchanges and other SROs to stop trading in a specific security pending the announcement of news, or to allow news to be absorbed by the market before trading continues. Since this situation would not constitute an emergency effecting essential systems and market infrastructure, it is not included within the definition of a market emergency.

emergency as quickly as possible after receipt of credible evidence that a market emergency exists.

• At least one hour's advance notice of a special meeting on a market emergency will be sent to each Board member by telephone and e-mail.

• The Executive Director, or his or her designee, will consult with the SEC prior to each special meeting if this is possible. (Note that consultation with SEC would be required by the interpretation of Rule G–17 governing trading halts. Thus, consultation with the SEC would have to occur prior to any formal declaration of market emergency even if it does not occur prior to the meeting.)

• The quorum of ten members generally necessary for a Board meeting is replaced for special meetings on market emergencies with a quorum of five members. The general requirement that a member be present from each of the three statutory categories (securities firm, bank dealer, public member) does not apply.

• The requirement in the proposed rule change that all Board members be sent a notice of the special meeting by both telephone and e-mail is to ensure that as many Board members as possible, including those from all three statutory categories, can be included in the meeting. While the five-person quorum requirement does not contain any distributional requirements, Board staff shall endeavor, to the extent circumstances permit, to have at least one broker-dealer, one bank, and one issuer representative at the special meetings. To that end, Board staff shall obtain from each Board member contract information that will help ensure the ability of the staff to get notice of a special meeting to such persons in market emergency situations.

• Board action at a meeting on a market emergency is limited to declaring a market emergency or ending a declared market emergency.

• A majority vote of members attending the meeting (not necessarily a majority of the Board) is required to take action.

• Once a market emergency has been declared, the Executive Director, or his or her designee, will schedule additional special conference call meetings on the market emergency within 24 hours after any request to do so by a Board member.

(2) Basis

The MSRB believes the proposed rule change is consistent with section 15B(b)(2)(C) of the Exchange Act, which provides that the MSRB's rules:

* * * be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade * * * and to protect investors and the public interest. * * *[5]

B. Self-Regulatory Organization's Statement on Burden on Competition

The MSRB does not believe that the proposed rule change will impose any burden on competition in that it applies equally to all dealers in municipal securities.

C. Self-Regulatory Organization's Statement of Comments on the Proposed Rule Change Received From Member, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for SEC Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the SEC may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the SEC will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the forgoing, including whether the proposed rule is consistent with the Exchange Act. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the SEC, and all written communications relating to the proposed rule change between the SEC 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 SEC's Public Reference Room. Copies of the filing will also be available for inspection and copying at the MSRB's principal offices. All submissions should refer to File No. SR–MSRB–2002–14 and should be submitted by February 14, 2003.

[5] 15 U.S.C. 78o–4(b)(2)(c).

For the SEC by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–1581 Filed 1–23–03; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47208; File No. SR–NASD 2002–157]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Regarding ACT Risk Management

January 16, 2003.

I. Introduction

On October 31, 2002, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its subsidiary The Nasdaq Stock Market, Inc. (''Nasdaq''), submitted to 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 regarding the risk management function provided by Nasdaq's Automated Confirmation Transaction Service. The proposed rule change was published for public comment in the **Federal Register** on December 16, 2002.[3] The Commission received no comments on the proposal. This order approves the proposal.

II. Description of the Proposed Rule Change

Nasdaq proposed changes to NASD Rule 6150 regarding the risk management function provided by Nasdaq's Automated Confirmation Transaction Service (''Act''). Upon approval of the proposed rule change, Nasdaq will permit members to voluntarily utilize the ACT risk management function, provided that they utilize another risk management tool of equal quality and that they and the correspondent firms for whom they clear trades continue to report clearing-eligible trades to ACT in compliance with applicable ACT rules.

III. Discussion

The Commission finds that the proposed rule change is consistent with

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 46948 (December 4, 2002), 67 FR 77117.

section 15A of the Act[4] and the rules and regulations thereunder applicable to a national securities association. In particular, the Commission finds that the proposed rule change is consistent with section 15A(b0(6) of the Act[5] which requires, among other things, that the rules of the association be designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and in general, to protect investors and the public interest.[6]

The ability of NASD clearing members to adequately assess the risk of their correspondent firms is critical to the protection of investors and the public interest, as required by the Act. Therefore, the Commission finds that the proposed rule change is consistent with the Act because the proposal seeks to ensure that all NASD clearing members retain the ability to monitor the trading activities and risk exposures of their correspondent firms, either by using the ACT risk management program, or another risk management tool comparable to ACT's risk management program. The proposed rule change also fosters cooperation and coordination with persons engaged in the regulating, clearing, settling, and processing of information with respect to and facilitating transactions in securities because it ensures that NASD clearing members utilize a risk management tool that monitors the acceptable levels of credit and risk exposure for correspondent firms, which helps to ensure the rapid and reliable comparison and settlement of transactions.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[7] that the proposed rule change (SR–NYSE–2002–57) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–1579 Filed 1–2–03; 8:45 am]

BILLING CODE 8010–01–M

[4] 15 U.S.C. 78o–3.

[5] 15 U.S.C. 78o–3(b)(6).

[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. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47191; File No. SR–NASD–2003–4]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed rule Change by the National Association of Securities Dealers, Inc. Relating to the Primex Auction System®

January 15, 2003.

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 January 14, 2003, the National Association of Securities Dealers, Inc., through its subsidiary The Nasdaq Stock Market, Inc. (''Nasdaq''), 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 Nasdaq. Nasdaq has designated this proposal as effective upon filing pursuant to section 19(b)(3)(A)(iii) of the Act,[3] and subparagraph (f)(2) of Rule 19b–5.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

1. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is filing a proposed rule change to continue operating Nasdaq's application of the Primex Auction System® (''Primex'' or ''System'') as a Pilot Trading System pursuant to Rule 196–5 of the Act,[5] until February 14, 2003, or until the Commission permanently approves Primex, whichever period is shorter. Pursuant to paragraph (f) of Rule 19b–5,[6] Nasdaq is filing this proposed rule change as effective immediately. This filing does not propose any rule language changes.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Section 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 Primex Auction System is a facility of Nasdaq that has been operating as a Pilot Trading System (''PTS''), as defined in Paragraph (c)(2) of Rule 19b–5 of the Act.[7] As such, Nasdaq was not required to file a proposed rule change under Rule 19b–4 of the Act[8] as long as the Primex maintained its status as a PTS. Under paragraph (c)(2) of rule 16b–5, a system must comply with three criteria to maintain its status as a PTS.[9] One such criteria is that, for each security traded in the PTS, the PTS can not trade more than one percent of the average daily consolidated trading volume of any such security, during at least two of the last four consecutive calendar months. Nasdaq represents that Primex exceeded this threshold for many securities. Therefore Nasdaq filed a proposed rule change seeking permanent approval of Primex.[10] Nasdaq also filed a proposed rule change to continue operating the System or up to six months while the Commission considered granting permanent approval.[11] This six-month period expired on October 31, 2002. On October 31, 2002, Nasdaq filed a proposed rule change, which was effective upon filing, to continue to operate Primex as a PTS until November 30, 2002.[12] On November 26, 2002, Nasdaq field a proposed rule change, which was effective upon filing, to continue to operate Primex as a PTS

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240,19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–5(f)(2).

[5] 17 CFR 240.19b–5.

[6] 17 CFR 240.19b–4(f).

[7] 17 CFR 240.19b–5(c)(2).

[8] 17 CFR 240.19b–4.

[9] Pursuant to Rule 129b-5(c)92), to qualify as a Pilot Trading System, a system must: (1) Be in operation for less than two years; (2) with respect to each security traded on such Pilot Trading System, during at least two of the last four consecutive calendar months, has traded no more than one percent of the average daily trading volume, in the United States; and (3) with respect to all securities traded on such Pilot Trading System, during at least two of the last four consecutive calendar months, has traded no more than 20 percent of the average daily trading volume of all trading systems operated by the self-regulatory organization.

[10] Securities Exchange Act Release No. 45983 (May 23, 2002) 67 FR 38152 (May 31, 2002).

[11] Securities Exchange Act Release No. 45982 (May 23, 2002) 67 FR 38163 (May 31, 2002).

[12] Securities Exchange Act Release No. 46756 (October 31, 2002), 67 FR 68221 (November 8, 2002).

until January 15, 2003.[13] The Commission is still considering Nasdaq's filing seeking permanent approval of Primex. Accordingly, Nasdaq is filing this proposed rule change to continue operating Primex as a PTS until February 14, 2003, or until the Commission grants permanent approval, which ever period is shorter. Primex continues to operate in the manner described in the Form Pilot filing, as amended.[14]

2. Statutory Basis

Nasdaq believes the proposed rule change is consistent with the provisions of sections 15A(b)(6)[15] and 11A(a)(1) of the Act.[16] Section 15A(b)(6) of the Act[17] requires the rules of the NASD to be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Section 11A(a)(1) of the Act[18] sets forth a finding of Congress that new data processing and communications techniques create opportunity for more efficient and effective market operations.

Nasdaq believes this proposed rule change is consistent with the NASD's obligations under the Act, as well as the finding of Congress, because it will allow Nasdaq to continue operating Primex while the Commission considers permanent approval. Among other things, the System provides members with an additional electronic, execution system, which is designed to provide members with flexibility in executing orders and the opportunity to obtain price improvement. To ensure the protection of investors, orders will not be executed at prices inferior to the National Best Bid or Offer.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)(iii) of the Act,[19] and subparagraph (f)(2) of Rule 19b–5 thereunder,[20] because the proposal will permit Nasdaq to continue operating Primex as a PTS while the Commission considers granting permanent approval. The proposal does not modify any rule or the operation of Primex.

At any time within 60 days of the filing of a rule change pursuant to section 19(b)(3)(A) of the Act,[21] the Commission may summarily abrogate the 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 proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–2003–4 and should be submitted by February 14, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[22]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–1580 Filed 1–23–03; 8:45 am]

BILLING CODE 8010–01–M

[13] Securities Exchange Act Release No. 46924 (November 27, 2002), 67 FR 72715 (December 6, 2002).

[14] Form Pilot—NASD–2001–01

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] 15 U.S.C. 78k–1(a)(1).

[17] 15 U.S.C. 78*o*–3(b)(6).

[18] 15 U.S.C. 78k–1(a)(1).

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(5).

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 200.30–3(a)(12).

STATE DEPARTMENT

[Public Notice 4220]

Overseas Security Advisory Council (OSAC) Meeting Notice: Closed Meeting

The Department of State announces a meeting of the U.S. State Department—Overseas Security Advisory Council on February 25 and 26, at the Biscayne Bay Marriott, Miami, Florida. Pursuant to Section 10 (d) of the Federal Advisory Committee Act and 5 U.S.C. 552b, (c)(1) and (4), it has been determined the meeting will be closed to the public. Matters relative to classified national security information as well as privileged commercial information will be discussed. The agenda will include updated committee reports, a world threat overview and a round table discussion that calls for the discussion of classified and corporate proprietary/security information as well as private sector physical and procedural security policies and protective programs at sensitive U.S. Government and private sector locations overseas.

For more information contact Marsha Thurman, Overseas Security Advisory Council, Department of State, Washington, DC 20522–1003, phone: 202–663–0533.

Dated: January 9, 2003.

Peter E. Bergin,

Director of the Diplomatic Security Service, Department of State.

[FR Doc. 03–1644 Filed 1–23–03; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE195; Special Conditions No. 23–135–SC]

Special Conditions: Adam Aircraft Industries; Model A500 CarbonAero Airplane, Installation of Full Authority Digital Engine Control (FADEC) System and the Protection of the System From the Effects of High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Adam Aircraft Industries Model A500 CarbonAero airplane. This airplane will have a novel or unusual design feature(s) associated with the installation of an engine that uses an electronic engine control system in place of the engine's mechanical system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is December 30, 2002. Comments must be received on or before February 24, 2003.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration (FAA), Regional Counsel, ACE–7, Attention: Rules Docket, Docket No. CE195, 901 Locust, Room 506, Kansas City, Missouri 64106, or delivered in duplicate to the Regional Counsel at the above address. Comments must be marked: Docket No. CE195. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Wes Ryan, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE–111, 901 Locust, Room 301, Kansas City, Missouri 64106; 816–329–4127 fax 816–329–4090.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

Interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or special condition number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. The special conditions may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. CE195.'' The postcard will be date stamped and returned to the commenter.

Background

On March 23, 2001, Adam Aircraft Industries applied for a type certificate for their new Model A500 CarbonAero. The Model A500 CarbonAero is powered by two reciprocating engines equipped with electronic engine control systems with full authority capability in place of the hydromechanical control systems.

Type Certification Basis

Under the provisions of 14 CFR part 21, § 21.17, Adam Aircraft Industries must show that the Model A500 CarbonAero meets the applicable provisions of 14 CFR part 23, as amended by Amendments 23–1 through 23–54, Federal Aviation Regulations part 36 with amendments effective on the date of certification, and any special conditions found necessary.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 23) do not contain adequate or appropriate safety standards for the Model A500 CarbonAero because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model A500 CarbonAero must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Special conditions, as appropriate, as defined in 11.19, are issued in accordance with § 11.38, and become part of the type certification basis in accordance with § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Model A500 CarbonAero will incorporate the following novel or unusual design features:

The Model A500 CarbonAero airplane will use an engine that includes an electronic control system with full engine authority capability.

Many advanced electronic systems are prone to either upsets or damage, or both, at energy levels lower than analog systems. The increasing use of high power radio frequency emitters mandates requirements for improved high intensity radiated fields (HIRF) protection for electrical and electronic equipment. Since the electronic engine control system used on the Adam Aircraft Model A500 CarbonAero will perform critical functions, provisions for protection from the effects of HIRF should be considered and, if necessary, incorporated into the airplane design data. The FAA policy contained in Notice 8110.71, dated April 2, 1998, establishes the HIRF energy levels that airplanes will be exposed to in service. The guidelines set forth in this Notice are the result of an Aircraft Certification Service review of existing policy on HIRF, in light of the ongoing work of the Aviation Rulemaking Advisory Committee (ARAC) Electromagnetic Effects Harmonization Working Group (EEHWG). The EEHWG adopted a set of HIRF environment levels in November 1997 that were agreed upon by the FAA, JAA, and industry participants. As a result, the HIRF environments in this notice reflect the environment levels recommended by this working group.

This notice states that a FADEC is an example of a system that should address the HIRF environments.

Even though the control system will be certificated as part of the engine, the installation of an engine with an electronic control system requires evaluation due to the possible effects on or by other airplane systems (*e.g.*, radio interference with other airplane electronic systems, shared engine and airplane power sources). The regulatory requirements in 14 CFR part 23 for evaluating the installation of complex systems, including electronic systems, are contained in § 23.1309. However, when § 23.1309 was developed, the use of electronic control systems for engines was not envisioned; therefore, the § 23.1309 requirements were not applicable to systems certificated as part of the engine (reference § 23.1309(f)(1)). Also, electronic control systems often require inputs from airplane data and power sources and outputs to other airplane systems (*e.g.*, automated cockpit powerplant controls such as mixture setting). Although the parts of the system that are not certificated with the engine could be evaluated using the criteria of § 23.1309, the integral nature of systems such as these makes it unfeasible to evaluate the airplane portion of the system without including the engine portion of the system. However, § 23.1309(f)(1) again prevents complete evaluation of the installed airplane system since evaluation of the engine system's effects is not required.

Therefore, special conditions are proposed for the Adam Aircraft Model A500 CarbonAero airplane to provide HIRF protection and to evaluate the installation of the electronic engine control system for compliance with the requirements of § 23.1309(a) through (e) at Amendment 23–49.

Applicability

As discussed above, these special conditions are applicable to the Model A500 CarbonAero. Should Adam Aircraft Industries apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101.

Conclusion

This action affects only certain novel or unusual design features on one model, Model A500 CarbonAero, of airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for the Adam Aircraft Industries Model A500 CarbonAero is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.17; and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Adam Aircraft Industries Model A500 CarbonAero airplanes.

1. *High Intensity Radiated Fields (HIRF) Protection.* In showing compliance with 14 CFR part 21 and the airworthiness requirements of 14 CFR part 23, protection against hazards caused by exposure to HIRF fields for the full authority digital engine control system, which performs critical functions, must be considered. To prevent this occurrence, the electronic engine control system must be designed and installed to ensure that the operation and operational capabilities of this critical system are not adversely affected when the airplane is exposed to high energy radio fields.

At this time, the FAA and other airworthiness authorities are unable to precisely define or control the HIRF energy level to which the airplane will be exposed in service; therefore, the FAA hereby defines two acceptable interim methods for complying with the requirement for protection of systems that perform critical functions.

(1) The applicant may demonstrate that the operation and operational capability of the installed electrical and electronic systems that perform critical functions are not adversely affected when the aircraft is exposed to the external HIRF threat environment defined in the following table:

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

The field strengths are expressed in terms of peak root-mean-square (rms) values.

(2) The applicant may demonstrate by a system test and analysis that the electrical and electronic systems that perform critical functions can withstand a minimum threat of 100 volts per meter peak electrical strength, without the benefit of airplane structural shielding, in the frequency range of 10 KHz to 18 GHz. When using this test to show compliance with the HIRF requirements, no credit is given for signal attenuation due to installation. Data used for engine certification may be used, when appropriate, for airplane certification.

2. *Electronic Engine Control System.* The installation of the electronic engine control system must comply with the requirements of § 23.1309(a) through (e) at Amendment 23–46. The intent of this requirement is not to re-evaluate the inherent hardware reliability of the control itself, but rather determine the effects, including environmental effects addressed in § 23.1309(e), on the airplane systems and engine control system when installing the control on the airplane. When appropriate, engine certification data may be used when showing compliance with this requirement.

Issued in Kansas City, Missouri on December 30, 2002.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–1664 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee to discuss rotorcraft issues.

DATES: The meeting will be held on February 11, 2003, 3 p.m. CST.

ADDRESSES: The meeting will be held at the Dallas Convention Center, Room D–175, 650 S. Griffin Street, Dallas, TX 75202, telephone (214) 939–2700.

FOR FURTHER INFORMATION CONTACT: Caren Centorelli, Office of Rulemaking, ARM–200, FAA, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8199, e-mail *caren.centorelli@faa.gov.*

SUPPLEMENTARY INFORMATION: The referenced meeting is announced pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II).

The agenda will include:

- Discussion and approval of the Critical Parts proposed Advisory Circular material package.
- Working Group Status Reports.
- Fatigue Tolerance Evaluation of Metallic Structures.
- Damage Tolerence and Fatigue Evaluation of Composite Rotorcraft Structure.
- FAA Status Report.
- Performance and Handling Qualities Requirements Notice of Proposed Rulemaking.

Attendance is open to the interested public but will be limited to the space available. The FAA will arrange teleconference capability for individuals wishing to join in by teleconference if we receive that notification 10 calendar days before the meeting. Arrangements to participate by teleconference can be made by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Callers outside the area will be responsible for paying long-distance charges.

The public must make arrangements to present oral statements at the meeting. Written statements may be presented to the committee at any time by providing 16 copies to the Assistant Chair or by providing the copies at the meeting.

If you are in need of assistance or require a reasonable accommodation for the meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT.** In addition, sign and oral interpretation, as well as a listening device, can be made available at the meeting if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Washington, DC, on January 17, 2003.

Anthony F. Fazio,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 03–1596 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss transport airplane and engine (TAE) issues.

DATES: The meeting is scheduled for February 4–5, 2003, beginning at 9 am on February 4. Arrange for oral presentations by January 31.

ADDRESSES: The Boeing Company, 1200 Wilson Boulevard, Room 234, Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Effie M. Upshaw, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–5075, or e-mail at *effie.upshaw@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to be held February 4–5 in Arlington, VA.

The agenda will include:

February 4

- Opening Remarks.
- FAA Report.
- Joint Aviation Authorities Report.
- Transport Canada Report.
- Executive Committee Report.
- Harmonization Management Team Report.
- ARAC Tasking Priorities and Cost-Benefit Analysis Methods Discussions.
- Engine Harmonization Working Group (HWG) Report and Approval.
- Loads and Dynamics HWG Report and Approval.
- Human Factors HWG Report.
- Mechanical Systems HWG Report.
- Ice Protection HWG Report.
- Design for Security HWG Report and Approval.

February 5

- General Structures HWG Report.
- Airworthiness Assurance Working Group Report.
- Powerplant Installations HWG Report.
- Written or verbal reports, as required, may be provided for the Continued Airworthiness Working Group and the following HWGs: Electromagnetic Effects, Flight Test, Avionics, Seat Test, Flight Control, Flight Guidance, System Design and Analysis, and Electrical Systems.

Three HWGs (Engine, Loads and Dynamics, and Design for Security) will be submitting final documents for approval:

1. The Engine HWG will seek approval of documents addressing engine critical parts integrity requirements;
2. The Loads and Dynamics HWG will seek approval of documents addressing ground load, landing loads conditions, and towing loads; and
3. The Design for Security HWG will seek approval of documents addressing aircraft features and protetions for the cabin, flight deck, and cargo compartments from the effects of an explosive device, including fire, smoke, and noxious vapors.

Attendance is open to the public, but will be limited to the availability of meeting room space and telephone lines. Visitor badges are required to gain entrance to the Boeing building where the meeting is being held. Please confirm your attention with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than January 31. Please provide the following information: full legal name, country of citizenship, and name of your company, if applicable.

For those participating by telephone, the call-in number is (206) 655–0054, Passcode 923071#. Details are also available on the ARAC calendar at *http://www.faa.gov/avr/arm/araccal/htm.* To ensure that sufficient telephone lines are available, please notify the person listed in the **FOR FURTHER INFORMATION CONTACT** section of your intent by January 31. Callers outside the Washington metropolitan area will be responsible for paying long distance charges.

The public must make arrangements by January 31 to present oral statements

at the meeting. Written statements may be presented to the committee at any time by providing 25 copies to the Assistant Executive Director for Transport Airplane and Engine issues or by providing copies at the meeting. Copies of the documents to be presented to ARAC for decision or as recommendations to the FAA may be made available by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

If you are in need of assistance or require a reasonable accommodation for the meeting or meeting documents, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT.** Sign or oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting.

Issued in Washington, DC on January 17, 2003.

Tony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 03–1600 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application 03–08–C–00–JAX, Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Jacksonville International Airport, Jacksonville, FL

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 Jacksonville International Airport under the provisions of the 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 24, 2003.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, Florida 32822.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to John D. Clark, III, President of the Jacksonville Airport Authority at the following address: 2010 Barnstormer Road, Jacksonville, Florida 32218.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Jacksonville Airport Authority under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Richard Owen, Program Manager, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, Florida 32822, (407) 812–6331, extension 19. 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 Jacksonville International Airport under the provisions of the 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On January 15, 2003, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Jacksonville Airport Authority was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 30, 2003.

The following is a brief overview of the application.

Proposed charge effective date: January 1, 2004

Proposed charge expiration date: July 1, 2007

Level of the proposed PFC: $4.50

Total estimated PFC revenue: $40,175,750

Brief description of proposed project(s): Checked baggage explosive detection system, Access control and communication center upgrades, and Centralized security checkpoint/west courtyard.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Non-scheduled/on-demand air taxi operators (ATCO) filing FAA Form 1800–31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Federal Aviation Administration, Airports Division, ASO–600, 1701 Columbia Avenue, College Park, Georgia 30337.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Jacksonville Airport Authority.

Issued in Orlando, FL, on January 15, 2003.

W. Dean Stringer,

Manager, Airports District Office.

[FR Doc. 03–1667 Filed 1–23–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Departmental Offices; Treasury Department Order Establishing the Alcohol and Tobacco Tax and Trade Bureau

AGENCY: Department of the Treasury, Departmental Offices.

ACTION: Notice.

SUMMARY: The Department of the Treasury is publishing a revision to Treasury Order 120–01 to formally establish within the Department the Alcohol and Tobacco Tax and Trade Bureau.

DATES: This Order is effective January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Marc A. Rigrodsky, Senior Counsel, Office of the Assistant General Counsel (General Law and Ethics), 202–622–1181 (not a toll-free call).

SUPPLEMENTARY INFORMATION: On November 25, 2002, the President signed into law the Homeland Security Act of 2002 (Pub. L. 107–296). Section 1111(c) of that Act transferred to the Department of Justice certain authorities, functions, personnel, and assets of the Bureau of Alcohol, Tobacco and Firearms (ATF), including the related functions of the Secretary of the Treasury. The Act also established within the Department of the Treasury the Tax and Trade Bureau (TTB).

On January 24, 2003, TTB assumes responsibility from ATF for the administration and enforcement of the following laws: chapter 51 (''Distilled spirits, wines, and beer'') and 52 (''Tobacco products and cigarette papers and tubes'') of the Internal Revenue Code of 1986 (Code); sections 4181 (Firearms—''Imposition of tax'') and 4182 (''Exemptions'') of the Code; and title 27, United States Code (''Intoxicating Liquors''). Revised Treasury Order 120–01 ensures that the TTB Administrator may exercise the authorities, perform the functions, and carry out the duties of the Secretary with respect to these laws. To avoid confusion over TTB's mission, the revised order also redesignates the TTB as the Alcohol and Tobacco Tax and Trade Bureau.

The text of the Order follows.

Dated: January 21, 2003.

Richard S. Carro,

Senior Advisor to the General Counsel, (Regulatory Affairs).

Treasury Order 120–01 (Revised)
Date: January 21, 2003.
Subject: Alcohol and Tobacco Tax and Trade Bureau

1. Establishment. By virtue of section 1111(d) of the Homeland Security Act of

2002, Title XI, Subtitle B, Pub. L. No. 107–296, 116 Stat. 2274, codified at 6 U.S.C. section 531(d), and by the authority vested in the Secretary of the Treasury (''Secretary'') under 26 U.S.C. 7801(a) and 31 U.S.C. section 321(b), the Tax and Trade Bureau is established within the Department.

2. Designation of the Tax and Trade Bureau as the Alcohol and Tobacco Tax and Trade Bureau. The Tax and Trade Bureau is designated as the Alcohol and Tobacco Tax and Trade Bureau (''TTB''). The head of the TTB is the Administrator (''Administrator''), who is appointed by the Secretary, and who shall perform duties as assigned by the Secretary or his designee.

3. Authorities, Functions, and Powers of the Administrator. The Administrator shall exercise the authorities, perform the functions, and carry out the duties of the Secretary in the administration and enforcement of:

a. Chapters 51 and 52 of the Internal Revenue Code of 1986;

b. Sections 4181 and 4182 of the Internal Revenue Code of 1986; and

c. Title 27, United States Code.

4. Former Authorities of the Director, ATF. The Administrator shall have all authorities delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms in effect on January 23, 2003, that are related to the administration and enforcement of the laws specified in paragraph 3. The Administrator shall possess full authority, powers, and duties to administer the affairs of and to perform the functions of TTB, including, without limitation, all management and administrative authorities and responsibilities similarly granted and assigned to Bureau Heads or Heads of Bureaus in Treasury Orders and Treasury Directives.

5. Completed Administrative Actions, Pending Proceedings, and Regulations.

a. All completed administrative actions of the Bureau of Alcohol, Tobacco and Firearms, including but not limited to orders, determinations, rules, regulations, personnel actions, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges and forms issued, adopted or executed in connection with the administration and enforcement of the laws specified in paragraph 3 on or before January 23, 2003, shall continue in effect until superseded or revised.

b. The terms ''Director, Bureau of Alcohol, Tobacco and Firearms,'' ''Director,'' and similar references wherever used in completed administrative actions issued, adopted or executed in connection with the administration and enforcement of the laws specified in paragraph 3 on or before January 23, 2003, shall mean the Administrator. The terms ''ATF officer'' or ''appropriate ATF officer,'' and all references to officers or employees of the Bureau of Alcohol, Tobacco and Firearms in completed administrative actions issued, adopted or executed in connection with the administration and enforcement of the laws specified in paragraph 3 on or before January 23, 2003, shall apply to officers or employees of TTB.

c. Proceedings pending in the Bureau of Alcohol, Tobacco and Firearms on January 23, 2003, relating to the administration and enforcement of the laws specified in paragraph 3, including but not limited to notices of proposed rulemaking, applications for licenses, permits, certificates, grants, and financial assistance, and personnel actions and other administrative proceedings, shall be under the authority of the Secretary and are delegated to the Administrator consistent with delegations from the Secretary to the Director of the Bureau of Alcohol, Tobacco and Firearms in effect on January 23, 2003.

d. Regulations for the purposes of carrying out the authorities, functions, and duties delegated to the Administrator may be issued by him with the approval of the Secretary or his designee.

6. *Redelegation.* The Administrator may delegate any of the authority vested under this Order. All delegations of authority in existence on January 23, 2003, by the Director of the Bureau of Alcohol, Tobacco and Firearms related to the administration and enforcement of the laws specified in paragraph 3 to positions established within TTB shall remain in effect until superseded or revised.

7. *Ratification.* Any action heretofore taken that is consistent with this Order is hereby affirmed and ratified.

8. *Privacy Act of 1974, as Amended, Systems of Records.* All systems of records of the Bureau of Alcohol, Tobacco and Firearms related to the administration and enforcement of the laws specified in paragraph 3 that were in effect on January 23, 2003, shall be TTB systems of records and shall continue to be covered by the **Federal Register** notice published on August 30, 2001, at 66 **Federal Register** 45893, until superseded or revised.

9. *Cancellations.*

a. Treasury Order 120–01, ''Establishment of the Bureau of Alcohol, Tobacco and Firearms,'' dated June 6, 1972, is cancelled.

b. Treasury Order 120–02, ''Trafficking in Contraband Cigarettes,'' dated December 5, 1978, is cancelled.

c. Treasury Order 120–03, ''Transfer of Functions to the Director, Bureau of Alcohol, Tobacco and Firearms, to Administer and Enforce, 26 U.S.C. 4181 and 4182, Relating to Excise Tax on Firearms,'' dated November 5, 1990, is cancelled.

d. Treasury Directive 15–12, ''Delegation of Authority to the Director, Bureau of Alcohol, Tobacco and Firearms, to Investigate Violations of 18 U.S.C. §§ 1956 and 1957,'' dated November 5, 2001, is cancelled.

10. *Authorities.* Section 1111 of the Homeland Security Act of 2002, Title XI, Subtitle B, Pub. L. No. 107–296, 116 Stat. 2274, codified 6 U.S.C. section 531, 26 U.S.C. Section 7801(a), and 31 U.S.C. Section 321(b).

11. *Effective Date:* January 24, 2003.

12. *Office of Primary Interest:* Alcohol and Tobacco Tax and Trade Bureau.

Kenneth W. Dam,

Acting Secretary of the Treasury.

[FR Doc. 03–1690 Filed 1–23–03; 8:45 am]

BILLING CODE 4810–25–P

Federal Register

Friday,
January 24, 2003

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 433 and 438

Medicaid Program; External Quality Review of Medicaid Managed Care Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433 and 438

[CMS–2015–F]

RIN 0938–AJ06

Medicaid Program; External Quality Review of Medicaid Managed Care Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes requirements and procedures for external quality review (EQR) of Medicaid managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs). It defines who qualifies to conduct EQR and what activities can be conducted as part of EQR. In addition, under certain circumstances, this rule allows State agencies to (1) use findings from particular Medicare or private accreditation review activities to avoid duplicating review activities, or (2) exempt certain Medicare MCOs and PIHPs from all EQR requirements. Also, this rule allows the payment of enhanced Federal financial participation (FFP) at the 75 percent rate for the administrative costs of EQRs or EQR activities that are conducted by approved entities.

EFFECTIVE DATE: These regulations are effective on March 25, 2003. Provisions that must be implemented through contracts with MCOs, PIHPs, and external quality review organizations (EQROs) are effective with contracts entered into or revised on or after 60 days following the publication date. States have up until March 25, 2004 to bring contracts into compliance with the final rule provisions.

FOR FURTHER INFORMATION CONTACT: Kristin Fan, (410) 786–4581.

SUPPLEMENTARY INFORMATION: 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 $10. 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**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO access, a service of the U.S. Government Printing Office. The Website address is *http://www.access.gpo.gov/nara/index.html.*

I. Background

A. The Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (BBA) added to the Social Security Act (the Act) a new section 1932 that pertains to Medicaid managed care. Most of the provisions of section 1932 of the Act will be implemented in accordance with the Medicaid managed care final rule that was published in the **Federal Register** on June 14, 2002 (67 FR 40988).

Section 1932(c) of the Act, added by section 4705 of the BBA, describes how quality measurement and performance improvement methods should be applied to Medicaid managed care programs through two specific approaches:

- All State agencies must develop and implement a quality assessment and improvement strategy that includes—(1) Standards for access to care; (2) examination of other aspects of care and services related to improving quality; and (3) monitoring procedures for regular and periodic review of the strategy. (This requirement was addressed in the Medicaid managed care final rule published June 14, 2002.)
- State agencies that contract with Medicaid managed care organizations (MCOs) must provide for an annual external, independent review of the quality outcomes, timeliness of, and access to the services included in the contract between the State agency and the MCO. (This requirement is addressed in this rule.)

Section 1932(c) of the Act also requires the Secretary—

In consultation with the States, to establish a method for identifying entities qualified to conduct external quality review (EQR) (section 1932(c)(2)(A)(ii) of the Act); and

In coordination with the National Governors Association (NGA), to contract with an independent quality review organization to develop the protocols to be used in EQRs (section 1932(c)(2)(A)(iii) of the Act).

Two other provisions of section 1932(c) of the Act are pertinent to this rule. They are (1) the requirement that the results of EQRs be made available to participating health care providers, enrollees and potential enrollees (section 1932(c)(2)(A)(iv) of the Act), and (2) the provision that a State agency may, at its option—

- Take steps to ensure that an EQR does not duplicate a review conducted either by a private independent accrediting organization or as part of an external review conducted under the Medicare program (section 1932(c)(2)(B) of the Act); and
- Exempt an MCO from EQR under certain specified conditions (section 1932(c)(2)(C) of the Act).

Section 4705(b) of the BBA amended section 1903(a)(3)(C) of the Act to provide for increased Federal financial participation (FFP) (75 percent) for the administrative costs the State incurs for EQR or EQR activities performed by specified entities under section 1932(c)(2)(A) of the Act.

B. Proposed Rule

On December 1, 1999 we published a proposed rule in the **Federal Register** (64 FR 67223) to implement the EQR statutory provisions. A summary of the specific provisions of the proposed regulations precedes each section of the comments and responses below. In the proposed rule, we discussed the two major purposes we had in developing the rule: (1) To provide flexibility for State agencies, and (2) to reflect the well-accepted advances in the technology of quality measurement and improvement. For a more detailed discussion of our basis and purpose for the approach taken in the December 1, 1999 proposed rule, see the preamble to that document at 64 FR 67223.

We received 29 comments from States, national and State organizations, health plans, advocacy groups, and other individuals on the December 1, 1999 proposed rule. The comments generally pertained to the types of entities that can be EQROs, EQR activities, nonduplication and exemption provisions, and dissemination of EQR rules. We carefully reviewed and considered all the comments we received.

C. Agency Information Collection Activities

On November 23, 2001 we published a notice in the **Federal Register** (66 FR 58741) to comply with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995. We invited public comment regarding the burden estimate or any other aspect of the EQR protocols we developed in accordance with section 1932(c)(2)(A)(iii) of the Act. This

provision required that we contract with an independent quality review organization to develop protocols to be used with respect to EQRs required by statute. In response to the requirement under section 1932(c)(2)(A)(iii) of the Act, we contracted with the Joint Commission on Accreditation of Health Care Organizations (JCAHO) which developed nine protocols and one appendix to several of the protocols in six quality improvement areas. We received 13 comments on the November 23, 2001 **Federal Register** notice. We carefully reviewed and considered all the comments we received.

II. Provisions of the Proposed Rule and Discussion of Public Comments

A. Basis, Scope and Applicability. (Formerly § 438.1), (Now § 438.310)

In this section we proposed to apply provisions to MCOs, prepaid health plans (PHPs), and entities with comprehensive risk contracts that are exempted by statute from the requirements in section 1903(m) of the Act, health insuring organizations (HIOs).

Comment: Many commenters supported the application of this rule to all three of the above types of entities. One commenter, though not opposed to the inclusion of PHPs, expressed concern about the cost of this requirement when applied to entities that provide services to small populations. The commenter suggested that the regulation apply only to entities to the extent feasible for the study being performed. Another commenter did not agree that the provisions should apply to PHPs and stated that there is no specific reference in Federal law to these organizations and that we have gone beyond the explicit language in section 1932(c) of the Act.

Response: We continue to believe these provisions should apply to most capitated health plans that are not MCOs, but that provide inpatient services. The Medicaid managed care final rule eliminated the term PHP and replaced it with two types of entities—prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). That rule, under the authority of section 1902(a)(4) of the Act, which authorizes the Secretary to establish requirements necessary ''for proper and efficient operation of the plan,'' applies the provisions related to a State's quality strategy to PIHPs but not to PAHPs. It does not apply these quality provisions to PAHPs because these entities provide a more limited array of services (for example, transportation or dental), and we do not believe it appropriate to require States to include these entities in their State quality strategies due to the burden it would impose. We, therefore, are revising this rule to be consistent with the Medicaid managed care final rule (§ 438.204(d)) and apply the EQR provisions to PIHPs as specified at § 438.310. We have also made changes to clarify the applicability of this rule to HIOs to be consistent with the Medicaid managed care final rule.

We do not agree with the commenter that we should exempt entities that have smaller enrolled populations from these requirements. Sections 1932(c)(2)(B) and (C) of the Act specifically identify the circumstances under which an entity may be fully or partially exempt from EQR.

Comment: One commenter asked if we intend to hold Indian Health Services (IHS) and 638 Tribal Facilities to the same standard as MCOs to ensure the quality of care provided to Native Americans.

Response: If an IHS entity or 638 Tribal Facility meets the definition of an MCO or PIHP, it would be subject to these provisions.

Comment: One commenter does not believe that primary care case management (PCCM) programs should be subject to these requirements. Another commenter believes that the activities in the December 1, 1999 proposed rule should be applied to PCCM programs.

Response: The statute does not extend the EQR requirement to PCCMs and the Conference Report, pages 859–860, makes clear that PCCMs were specifically excluded from the requirements. We have used the authority of section 1902(a)(4) of the Act to extend the EQR provision to PIHPs because, like MCOs, PIHPs provide inpatient services and are capitated. If a PCCM meets the definition of a PIHP, then it would be subject to the provisions of this rule. However, traditional PCCMs are reimbursed on a fee-for-service (FFS) basis along with a case management fee. Under that reimbursement arrangement, the PCCM would not be subject to the EQR requirements.

Comment: Many commenters recommended that external review also examine subcontracting managed care entities. One commenter suggested that the definition of quality be expanded to include services provided through subcontracts with MCOs.

Response: The MCO or PIHP is fully responsible (§ 438.230 of the Medicaid managed care final rule) for all activities delegated to another entity. Therefore, the EQR should include information on all beneficiaries and the structure and operations of all entities that provide Medicaid services under either the prime contract or subcontract. At § 438.320, we revised our definition of EQR to clarify our intent that the EQR provisions apply to all services received by Medicaid beneficiaries regardless of whether those services are provided by the MCO or PIHP directly or through a subcontract.

Comment: One commenter is concerned that this rule applies the EQR requirement to PHPs despite the BBA's statutory reference only to organizations under section 1903(m) of the Act. The commenter asked us to clarify whether we intend to apply these requirements to any entity that is paid on a prepaid capitation basis for services furnished to enrollees, even if the PHP is not at any financial risk for those services.

Response: As noted in an earlier response, the EQR provisions will apply to a PIHP defined in the Medicaid managed care final rule as an entity that ''provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangement that do not use State plan payment rates and that provides, arranges, or otherwise has the responsibility for the provision of any inpatient hospital or institutional services for its enrollees * * *'' We do not apply these quality provisions to PAHPs because these entities provide a more limited array of services (for example, transportation or dental), and we do not require States to include these entities in their State quality strategies due to the burden it would impose. The application of this rule to PIHPs is not based on section 1903(m) of the Act. It is based on section 1902(a)(4) of the Act that authorizes the Secretary to establish requirements necessary ''for the proper and efficient operation of the plan.'' We believe this is consistent with congressional intent.

PIHP and PAHP designation is not based on whether an entity is at financial risk for services provided. Designation is based on prepaid capitation payments for a scope of services. Even though there will be few PIHPs that are not at financial risk, due to the scope of services these entities provide (for example, inpatient services), we believe they should be subject to EQR provisions.

B. Definitions (Formerly § 438.2), (Now § 438.320)

This section of the proposed rule defined ''EQR'' and ''EQRO.'' It also defined the terms ''quality'' and ''validation'' as they pertain to EQR.

Comment: One commenter concurred with our requirement that EQR be a multipronged approach which recognizes that none of the activities alone can ensure quality in the complex Medicaid population. One commenter supported the definitions as proposed.

Response: We appreciate that the commenters agreed with our approach to EQR and the proposed definitions. We have retained the multipronged approach to EQR as proposed in the proposed rule.

Comment: One commenter asked that the definition of quality include assessments of structure and process as well as measurements of health and functional outcomes. Several commenters recommended that the definition of quality include both clinical and nonclinical measures of consumer satisfaction and define quality in a way that would be meaningful to people with disabilities. One commenter stated that this definition should address the multifaceted needs of people who have chronic and disabling conditions, for whom there is little likelihood of demonstrable improvement. The commenter recommended that we convene focus groups of consumers, including people with disabilities and families of children with disabilities, to identify how quality should be defined from the consumer's perspective and that the definition should not focus solely on health outcomes. One commenter concurred with the definition of quality as proposed.

Response: We agree with the commenter that the proposed definition of quality did not address situations when beneficiaries have conditions where maintenance or improvement of health outcomes is not likely. We have, therefore, revised the definition to mean the degree to which an MCO or PIHP increases the likelihood of desired health outcomes through the provision of health services that are consistent with current professional knowledge. The revision is consistent with the Institute of Medicine's definition of quality. We do not agree with the remaining recommendations by commenters on how to revise the definition of quality because we think that the commenters' concerns are addressed by other provisions of the regulation. Under § 438.358, we identify three activities that must be conducted to provide information for the EQR. These activities also are required in the Medicaid managed care final rule. They include: (1) The review of compliance with structural and operation standards; (2) the validation of performance measures;[1] and (3) the validation of performance improvement projects. The optional EQR-related activities are activities that some States currently conduct as part of EQR and we believe are also appropriate to an assessment of quality (such as consumer surveys). We are providing States with the flexibility to determine which, if any, of these optional activities will be included in the EQR and what types of performance measures and performance improvement projects to require of their contracting MCOs and PIHPs. We suggest in the performance improvement project protocol that projects be conducted to address both clinical and nonclinical areas that cover the various categories of beneficiaries and services provided. We also note, as stated in the Medicaid managed care final rule, that EQR is a part of the State's quality strategy, and therefore, States are to provide for the input of Medicaid beneficiaries and other stakeholders in this component of the strategy.

Comment: One commenter suggested amending the definition of EQR to read ''* * * quality of health care services furnished or contracted for by each MCO * * *''

Response: We agree with this comment and, as stated previously, have revised the final rule to clarify our intent that the EQR provisions apply to all services received by Medicaid beneficiaries regardless of whether those services are provided by the MCO or PIHP directly or through a subcontract (§ 438.320).

Comment: Several commenters stated that the definition of EQR too narrowly limits the scope of EQR because the definition implies that EQR is primarily concerned with analysis and evaluation of data rather than with collection of data. One of the commenters expressed concern that this would limit the EQRO's ability to identify and bring to the State's attention individual quality of care concerns revealed during data abstraction, or to provide provider-specific feedback on performance measures. The commenter recommended that the rule avoid any reference to ''aggregate'' information in the definition of EQR. One commenter recommended that the definition of EQR include the development of aggregated data. Another commenter stated that external review should not be limited to the review of information. The commenter believes the external review of plans should include an on-site review of provider practices and procedures and that data alone are insufficient to evaluate performance.

Response: We do not agree that the definition of EQR limits the scope of EQR. We define EQR as the analysis and evaluation of aggregated information. That aggregated information, according to this rule, must be obtained from activities that are consistent with protocols, as defined in this rule, to ensure that data to be analyzed are collected using sound methods widely used in the industry. For each activity, as specified in § 438.364, the entity conducting the activity must report on the objectives, technical methods of data collection and analysis, a description of the data obtained, and conclusions drawn from each activity. Therefore, as part of these activities, the entity conducting them will need to identify and assess quality of care concerns revealed by the activities. The EQR analysis will incorporate findings from all activities, including the evaluation of MCO or PIHP structure and operations. The findings of the overall analysis will need to include an assessment of the strengths and weakness with respect to quality, timeliness, and access of care, and make recommendations for MCO or PIHP improvement in the EQR results as required under § 438.364. Further, we note that under the BBA statutory provisions, EQR is a review of a Medicaid MCO under contract to the State. EQR of individual providers or provider practices is not provided for in the BBA. We believe that the appropriate unit of analysis of EQR is the MCO and PIHP, not individual practitioners.

C. State Responsibilities (§ 438.350)

This section of the proposed rule set forth the State's responsibilities related to EQR. We proposed that each State agency that contracts with MCOs, PHPs, or other entities that have comprehensive risk contracts must, except as provided in § 438.362, ensure that (1) An annual EQR is performed for these contracting entities by a qualified EQRO; (2) the EQRO has sufficient information to use in performing the review; (3) the information that the State agency provides to the EQRO is obtained through methods consistent with protocols specified by CMS; and (4) the results of the EQR are made

[1] In the Medicaid managed care final rule under § 438.240(c)(2) we permit States to calculate performance measures on the MCO's/PIHP's behalf in place of the MCO/PIHP calculating and reporting performance measures to the State. Under this circumstance, the validation of MCO/PIHP performance measures is not required as a mandatory activity but the State must submit the State-calculated performance measures to the EQRO for the EQR function as specified under § 438.358(b)(2). This issue is addressed later in the preamble in response to a comment.

available, upon request, to specified groups and to the general public.

Section 1932(c)(2)(A) of the Act requires that each contract with an MCO ''provide for an annual (as appropriate) external independent review, conducted by a qualified independent entity * * *'' In this section we interpreted the parenthetical statement (for which there is no explanation in the legislative history) to be a reference to those MCOs that may be exempted from EQR under section 1932(c)(2)(C) of the Act on the basis of ''deemed compliance.'' We invited comment on other possible interpretations, which are discussed at the end of this section.

Comment: One commenter noted they concurred with this section of the rule.

Response: We appreciate the commenter's support for the provisions in this section of the proposed rule and retain the provision that requires the State to ensure that the EQRO has information obtained from EQR-related activities and that the information provided is obtained through methods consistent with the EQR protocols established under § 438.352 in this final rule.

Comment: Several commenters asked us for a definition, or the criteria that we will use to determine if State-established protocols are consistent with those developed by us. One of the commenters noted that it would be difficult for all States to follow a single set of protocols because State Medicaid programs vary as to structure, capacity, funding, and governing laws. One commenter asked that we also establish criteria for denominators, numerators, and units of measurement for performance measures. Other commenters concurred with the requirement to use protocols that are ''consistent with'' rather than ''identical to'' those developed by us to accommodate the rapidly changing field of quality assessment and improvement.

Response: Section 1932(c)(2)(A)(iii) of the Act required the Secretary in coordination with the National Governors Association, to contract with an independent quality review organization to develop protocols to be used in EQR. In planning for the development of the protocols, we had to determine the level of detail to be specified in each of the protocols. Because States have flexibility to choose what aspects of quality to measure and in order to accommodate different methodological approaches to studying quality, we contracted for the development of protocols that specified activities and steps of data collection and analysis that would produce valid and reliable information. These apply regardless of the data collected or the topics that States choose. Protocols will be considered ''consistent'' with ours to the extent that they affirmatively address each element specified in § 438.352, including the activities and steps for collecting data. We have revised the regulations under § 438.352(c) to clarify that instead of following ''detailed procedures,'' the EQR-related activities follow ''activities and steps'' specified for accurate, valid, and reliable data collection.

Comment: One commenter recommended that external review be required every 3 years rather than on an annual basis. The commenter noted that the National Committee for Quality Assurance (NCQA) requires a standard external review every 3 years and believes that this rule and the protocols should not set a standard more stringent than the industry standard.

Response: Section 1932(c)(2)(A)(i) of the Act clearly states that contracts ''shall provide for an annual (as appropriate) external independent review.'' We discuss later in this preamble why the parenthetical was not intended to modify what is otherwise an explicit requirement that EQR be conducted annually. An annual EQR has been a statutory requirement since 1986 under section 1902(a)(30)(C) of the Act. Pub. L. 106–113 made it clear that the provision was being replaced by 1932(c)(2) of the Act. We further note that the EQR described in this rule is very different from the accreditation review performed by NCQA. However, in the monitoring for compliance with the standards protocol that provides accreditation-like data, we only provide that information from a review of compliance with standards be generated every 3 years. This is consistent with the industry standard.

Comment: One commenter asked for confirmation that § 438.356(a) allows for EQR for a single MCO or PIHP to be performed by more than one EQRO.

Response: We are revising proposed § 438.356(a) to clarify that while we allow a State to contract with different EQROs to conduct EQR and EQR-related activities for a single MCO or PIHP, we believe and continue to require that the final analysis of all the information, as distinguished from the EQR-related activities, be performed by a single EQRO. This provides State flexibility to use different contractors to conduct different activities. Section 438.350 addresses the analysis and evaluation of information derived from mandatory and any optional activities. We believe that a single EQRO should perform this function to ensure that one entity receives all the available information and draws the overall conclusions about a particular MCO or PIHP. To clarify our intent to require that one EQRO perform the overall analysis (that is, conduct EQR) but that multiple EQROs may conduct EQR-related activities, we revised the language from the proposed rule to (1) remove the reference to ''other related activities'' in the definition of EQR, (2) add the reference to EQR-related activities to the definition of EQRO at § 438.320, and (3) add the reference to EQR-related activities to § 438.370 which provides for the 75 percent enhanced match. We also revised § 438.356(a) to clarify that States may only contract with one entity for EQR but may contract with multiple entities to conduct EQR-related activities.

Comment: One commenter recommended the addition of language allowing States the option to employ alternative quality assessment and improvement methods approved by CMS to substitute for the EQR requirements. The revised language should emphasize the State's responsibility under section 1932(c)(1)(A) of the Act to develop and implement a quality assessment and performance improvement (QAPI) strategy that includes, but is not restricted to, EQR-related activities. If CMS seeks to define minimum specifications for a State's QAPI strategy, those specifications should be set out in a proposed rule and subject to public review and comment.

Response: Our Medicaid managed care final rule outlined the elements of a State quality strategy, of which EQR is one element. States have the flexibility to determine how to ensure the quality strategy elements are designed and implemented. The public had the opportunity to review and comment on the proposed elements in the Medicaid managed care proposed rule published August 20, 2001 in the **Federal Register** (66 FR 43614). The EQR proposed rule addresses EQR in greater detail than does the managed care final rule, including what activities can be funded under the EQR enhanced matching rate. In this final rule, we describe optional EQR-related activities for which a State can obtain the enhanced Federal match under § 438.370. We believe we have provided States with the flexibility to design their EQR to best meet State needs while at the same time ensuring, through the three mandatory activities, that essential quality activities are conducted.

Comment: Several commenters recommended that we require that States coordinate their EQR with the State's quality strategy established

under § 438.200 through § 438.204 of the Medicaid managed care rule and that EQR evaluate compliance with standards for quality, timeliness, and access in § 438.206 through § 438.242 of the Medicaid managed care proposed rule.

Response: We agree with the commenter. The Medicaid managed care final rule provides that an annual EQR be one element of a State's quality strategy. The EQR rule provides that information from a review of compliance with structural standards (including quality, timeliness, and access) be used in the EQR. Because of this we believe that the two rules together will require each State to coordinate its EQR with all other components of its State strategy.

Comment: One commenter agreed with our interpretation of the statutory provision requiring an external review annually ''as appropriate'' as being a reference to the deemed compliance provision. The commenter also suggested that reasons for not conducting a review be expanded to include (1) when the MCO is new and there are no historical records and (2) when the population of the MCO is too small to conduct a particular study.

Response: We disagree that newly contracting MCOs and PIHPs should not be subject to EQR. New MCOs and PIHPs will be required to meet structural standards, and we believe that information about MCO and PIHP compliance with these standards should be subject to EQR. We understand that the calculation of performance measures and the implementation of performance improvement projects require time to complete and may not be available at the time of the EQR. Therefore, while we acknowledge there are mandatory activities for EQR that may not be possible the first year of an MCO's or PIHP's operations, we do not agree that the MCO or PIHP should be entirely exempt from EQR. We also do not agree that small population size should be a reason to exempt an MCO or PIHP from EQR. Rather, the State, or MCO or PIHP if the State permits, should choose a performance improvement topic for which the entity has a sufficient number of enrollees to conduct a valid study.

Comment: Several commenters believe that the ''as appropriate'' parenthetical allows CMS the discretion to interpret EQR time frames more broadly and to give States discretion to require EQRs less frequently than annually. One commenter suggested that ''as appropriate'' modifies the word ''annual,'' not ''review.''

Response: We do not believe that the Congress intended for us or the States to have discretion to provide for reviews less frequently than annually. As discussed above, section 1932(c)(2) of the Act replaces a statutory requirement for annual review that has applied since 1986. There is no indication in the legislative history that the Congress intended to change this. To the contrary, there is a persuasive alternative explanation for the Congress having inserted the parenthetical language. Section 1932(c) of the Act, unlike section 1902(a)(30)(C) of the Act has exemptions from the EQR requirement. Annual reviews for exempt entities are not appropriate.

Comment: One commenter interpreted the parenthetical to allow States to conduct reviews more frequently, not less frequently. If the EQR identified problems, the EQRO could be authorized to conduct follow-up evaluations, as appropriate, to ensure progress toward compliance.

Response: We do not agree with the commenter's interpretation because we believe that if problems are identified in the reports that the EQRO provides the States, the States can follow-up on any corrective action. Because we were not persuaded by any of the comments received for a different or additional interpretation of the parenthetical ''as appropriate,'' we are retaining in the final rule the interpretation that it refers to ''deemed compliance'' under section 1932(c)(2)(C) of the Act.

D. External Quality Review Protocols (§ 438.352)

In this section, we proposed that EQR protocols must specify: (1) The data to be gathered, that is, the substantive areas to be covered by the protocol; (2) the sources of the data; (3) detailed procedures to be followed in collecting the data to promote its accuracy, validity, and reliability; (4) the proposed methods for valid analysis and interpretation of the data; and (5) all instructions, guidelines, worksheets and any other documents or tools necessary for implementing the protocol. At the time the proposed rule was published, the protocols were under development. The strategy and timeline for protocol development were undertaken in response to BBA language that directed the Secretary to ''contract with an independent quality review organization'' to develop the protocols. The contract procurement process and scope of work necessitated that the protocols be completed after publication of the proposed rule. On November 23, 2001, we published a notice in the **Federal Register** (66 FR 58741) announcing the completion of the protocols and asking for comment on their burden or any other aspect of the protocols. Comments received on the November 23, 2001 **Federal Register** notice are addressed later in this preamble.

In developing the protocols, we instructed our contractor to draw from existing protocols that have been tested for reliability and validity and that have been used in the public and private sectors to conduct reviews of the quality of MCO and PHP services, consistent with current industry practice. We also expressed a preference for protocols that are in the public domain. The principle reason for not including the protocols in our regulation is because quality measurement is a rapidly changing field. The protocols must be revised regularly to reflect the changing state-of-the-art in quality improvement. Protocols developed in the private sector for validation of performance measures and administration of consumer surveys are usually revised annually. The delays inherent in revising regulations would make it difficult to make frequent changes. In addition, the protocols are detailed and lengthy, as they provide optional worksheets and recording documents in addition to the required activities and steps.

We proposed that all activities that provide information for EQR must be undertaken consistent with the protocols. Use of the CMS protocols or others consistent with ours will ensure that the conduct of the activities is methodologically sound, thereby maintaining a standard of quality for the review. However, by requiring protocols that are ''consistent,'' rather than ''identical,'' with those that we specify, we leave the States free to improve their protocols continuously, as the art and science of quality measurement improves.

Comment: One commenter asked that the protocols not pose an undue burden on physicians, clinical, or nonclinical personnel, noting that many physicians contract with more than one MCO and that duplicative information gathering should be avoided.

Response: EQR focuses on the MCO's and PIHP's structure and processes, and their ability to manage access to and provide quality services to Medicaid beneficiaries. The review process is not directed to individual physicians or other clinical or nonclinical personnel. However, it will be necessary for MCOs and PIHPs to request information from providers in order to conduct some of the activities required in this regulation. In recognition of the potential for burden, our request for proposal (RFP) to procure the development of the

protocols specified that, ''the protocols must be sensitive to the effect the burden to produce or provide additional data and information will have on organizations' ability to carry on their day-to-day operations.'' We also specified that the protocols incorporate, as much as feasible, the tools, techniques, and methods to assess and improve health care quality already in place in the private sector. As a result, we believe the protocols impose the minimal additional burden necessary to carry out the statutory requirement.

Comment: In order to allow for parents to choose an MCO for their child on the basis of pediatric care, one commenter stated that the protocols should require that data on pediatric populations be analyzed apart from data on the MCO's adult population. The commenter also suggested that pediatricians and pediatric subspecialists have input into the development of the protocols.

Response: As required by statute, the protocols were developed by an independent quality review organization. In the scope of work for that contract, we required that the organization convene a panel composed of (1) current EQRO contractors; (2) CMS representatives; (3) State Medicaid agency directors, (4) managed care directors and quality system managers; (5) State licensure agencies; (6) advocacy groups; (7) health plans; (8) accrediting agencies; and (9) other experts in the area of quality improvement. A number of these panel members had experience with child health issues. We published a notice in the **Federal Register** on November 23, 2001 announcing the completion of the protocols and asking for comment on their burden. At the same time, the protocols were also made available on our website. The protocols are a methodologically sound set of generic instructions that will guide the reviewer in assessing quality. These instructions can be used for the entire Medicaid population in the MCO or PIHP or, in some instances, can be used for subpopulations such as children who receive Medicaid services. Some protocols address how MCOs, PIHPs, and States can stratify by specific populations, such as older adults or children with special health care needs. In addition, we note that States currently use many performance measures related to care for children. We, therefore, do not believe it necessary for the protocols to address pediatric populations apart from adult populations.

Comment: One commenter asked that we provide a definition for and examples of performance measures and performance improvement projects. One commenter agreed that we should not include the protocols in the proposed rule, given the dynamic state of quality evaluation and measurement. The commenter asked that we clarify what protocols for ''calculating performance measures'' means, that is to clarify whether it refers to protocols for the development of measures, the calculation of performance thresholds from reported measures, or some other EQR function.

Response: The definition and explanations of performance measurement and performance improvement projects are discussed in both the Medicaid managed care final rule and, in detail, in the protocols for calculating performance measures, validating performance measures, conducting performance improvement projects and validating performance improvement projects. In general, we refer to performance measurement as the calculation of the rate at which a desired event occurs. Readers are referred to the protocols available at *http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp* for further discussion.

Comment: Many commenters believed that the protocols should require MCOs to report on Americans with Disabilities Act (ADA) compliance issues for themselves and their providers to ensure that persons with disabilities have an opportunity to benefit from covered services that is equal to persons without disabilities.

Response: Compliance with the ADA provisions is addressed in the Medicaid managed care final rule and in the EQR protocol entitled Monitoring Medicaid Managed Care Organizations (MCOs) and Prepaid Inpatient Health Plans (PIHPs)—a protocol for determining compliance with the Medicaid managed care final rule provisions. It is the State's responsibility to ensure that its MCOs and PIHPs comply with Federal laws, including ADA.

Comment: Many commenters recommended that the sample for calculating performance measures, including baseline and follow-up measures for performance improvement projects, should be sufficient to look at specific measures of clinical care; and that the protocols should describe how reviewers will analyze the quality of care when data are missing. The commenters also believed that the protocols should require that MCOs use a common core of widely used, objective performance measures that are issued annually and revised as needed to reflect advances in performance measurement, that these measures and their methods of calculation be publicly available, and that they include measures for persons with special health care needs. The commenters also recommended that MCOs be required to (1) collect specified HEDIS measures; (2) conduct the Consumer Assessment of Health Plan Study (CAHPS) survey; and (3) conduct a focus study annually of specialized services to persons with special health care needs. The EQR should evaluate these measures in making findings on the quality of care. Finally, the commenters asked that instructions be provided on how to adapt the measures to FFS and PCCM settings and for those enrolled less than 12 months.

Response: As stated before, the protocols are a set of methodologically sound generic instructions that will guide a reviewer in assessing quality. The protocols include instructions on proper sampling methodology, assessing missing data, and processes for analyzing data. The protocols do not specify which performance measures are to be used. Performance measures are chosen by the State or MCO or PIHP and will vary over time. The Medicaid managed care final rule gives us the authority to require specific performance measures and levels if we decide to do so in the future. The results of the EQR, however, will be made available to the public upon request and will identify the specific measures collected, the technical methods of data collection and analysis, and the conclusions drawn from the data.

The BBA placed the requirement for EQR on capitated managed care programs, but not on FFS or PCCM settings. Therefore, we do not in this rule provide an explanation of how to adapt these activities to the FFS/PCCM environment. We do, however, encourage States to address the quality of care provided in these service delivery systems. Through a new partnership initiative with State Medicaid and State Children's Health Insurance Programs (SCHIP), we will be discussing how best to apply performance measures to these two delivery systems.

Comment: One commenter asked that we retain the ability of State agencies to continue to improve the protocols as advancement occurs in the art and science of quality measurement. Several commenters stated that because the protocols may quickly become out of date because the field of quality improvement is constantly changing, they should not be promulgated as regulation. These commenters were concerned about CMS developing

detailed and lengthy protocols instead of either guidelines for States or streamlined protocols that specify only the basics for ensuring statistically sound, reliable, and valid results. One of these commenters stated that our intent appears to limit State flexibility and suggested that CMS significantly simplify the protocols to ensure feasibility for State agencies. This commenter also asked that CMS obtain State input on the draft protocols.

Several commenters believed that CMS should require that States use the protocols. One commenter felt that the proposed rule allows States to develop their own external review protocols. This commenter asked CMS to mandate the use of the protocols in order to comply with section 1932(c)(2)(A)(iii) of the Act which directs the Secretary to ''* * * contract with an independent quality review organization to develop protocols to be used in external reviews conducted * * *'' The commenter asserted that mandating the protocols would promote efficiency, lessen burden on the States, and promote the development of standardized data and information about services provided in Medicaid managed care.

Response: This regulation provides States with the option to use the protocols developed by us or protocols that are consistent with our protocols. We believe that by allowing States to use ''consistent'' protocols, States will be able to improve the protocols over time as the state-of-the-art advances and at the same time ensure that reliable and valid methods are used when conducting EQR-related activities.

The protocol documents include a discussion of the activities and steps necessary to soundly conduct the quality assessment function addressed by each protocol. In addition, each protocol includes guidance on how to implement the essential elements of the protocol as well as optional worksheets and appendices that States may use at their discretion. The activities and steps contained in the protocols are generic, relatively brief, but contain the essential components for a methodologically sound review that the statute envisions. Therefore, we believe that the protocols allow for State flexibility while ensuring the methodologically sound and valid EQR.

Comment: Several commenters noted that it is difficult to determine the full extent of the impact of the protocols on EQR activities until they are published. These commenters stated that they hope the protocols will respect States' individuality and provide flexibility whenever possible to allow for tailoring of EQR activities to local conditions and circumstances. One commenter further stated that there are many clinical guidelines and protocols that are already published, easily available, and in current use (for example, those developed by the Agency for Health Care Policy and Research (AHCPR) now the Agency for Health Care Research and Quality (AHRQ), American Heart Association, etc * * *) that are not mentioned in the proposed rule.

Another commenter stated that the protocols should be subject to full public scrutiny because they carry the full weight of the regulation. The commenter believes the protocols significantly exceed both the intent of the Congress in the BBA and the proper role of this regulation. Specifically, the commenter noted that the statute does not specify the activities that the protocols should address or other details included. The commenter was also concerned that States will find the 75 percent match for EQR activities a strong incentive to outsource this function, which the commenter believes appropriately rests with the government. As a result, this commenter believes that activities now done by the State according to locally developed protocols will be shifted to contract staff to be performed using externally derived standard protocols.

Another commenter asked that current State practices not be totally dismissed and that consideration be given to the quality improvement system for managed care (QISMC) standards and how they can be incorporated into the EQR process.

Response: We published a notice in the **Federal Register** on November 23, 2001 (64 FR 58741) announcing the completion of the protocols and asking for comment on their burden. At that time, the protocols were also made available on our website. Comments on the protocols and our responses are incorporated in this preamble. We believe the protocols are generic and can be used by all States. They are not clinical protocols like those published by AHCPR (now AHRQ), the American Heart Association, and other organizations. We believe that the protocols are consistent with the intent of the Congress in the BBA. We also note that we have provided States with great flexibility to conduct all EQR-related activities, allowing States to perform EQR-related activities either themselves or through the use of contractors, as long as they are performed consistent with our protocols. While the enhanced Federal financial match for EQR-related activities is not available under the statute if conducted by State personnel, other provisions of Medicaid law provide for enhanced Federal financial match for qualified medical activities when conducted by State staff who qualify as skilled and professional medical personnel.

The protocols are based on existing protocols already in use in the public and private sector. The contractor used QISMC guidelines as well as other public and private sector protocols in developing all the protocols. With respect to the QISMC standards (as opposed to their interpretive guidelines) we note, for Medicaid, that the QISMC standards were superceded by the Medicaid managed care final rule. QISMC standards are no longer current for the Medicaid program. For each protocol developed, specific information can be found in the protocol regarding which public and private sector protocols were reviewed and the extent to which they were incorporated.

Comment: One commenter was concerned that the JCAHO does not have a traditional background in this area and may take a different approach than NCQA.

Response: The BBA specified that the protocols be developed by an ''independent quality review organization.'' The JCAHO was selected through an open competitive procurement process, which required them to provide evidence of their experience in protocol development. In addition, they developed the EQR protocols using existing protocols widely used in the public and private sector, including protocols used by national accrediting organizations, and national consulting firms which have developed quality measurement tools for us in the past.

Comment: One commenter asked if health plans will have to create an entirely different audit response to the protocols in addition to responding to the existing standards of NCQA and of other State entities.

Response: Because the protocols were based on quality assessment approaches already in use by public and private quality oversight organizations, we believe that the methods MCOs and PIHPs use to respond to existing private and public sector audits will be able to be used to respond to EQR. In addition, the nonduplication provisions under § 438.360 are revised in the final rule to allow States in certain circumstances to exempt both Medicare+Choice (M+C) organizations and MCOs and PIHPs meeting standards of national accrediting organizations approved and recognized by CMS for M+C deeming

from compliance with some structural standards.

Comment: One commenter stated that the protocols being developed are, in fact, EQR-related activity protocols and that there does not appear to be any protocol that will guide the analysis and evaluation of the data and information provided by these EQR-related activities. This may cause the analysis and evaluation to vary due to lack of equivalent specifications for these processes. The commenter recommended that the rule more clearly define requirements for EQR and distinguish between EQR and EQR-related activities.

Response: The commenter is correct that we do not provide a protocol for the analysis and evaluation of information provided as a result of the EQR activities in the aggregate. We do not believe that we should develop a protocol for the analysis and evaluation of all EQR information. The information derived from EQR activities will vary enormously. For instance, the variation in the types of services provided and the populations covered under the MCO and PIHP contract will impact the performance measures chosen and performance improvement projects to be conducted. Other activities are optional for States. The approach to analysis depends upon the findings of the individual EQR-related activities and we expect these findings to be as individual as the MCOs and PIHPs being reviewed. Therefore, we do not believe that we can adequately predict all the possible variations of information that will be provided to an EQRO and, therefore, we do not provide for a protocol on how to conduct an analysis and evaluation of this information. We believe it is more appropriate for us to require that the activities that provide information for the analysis and evaluation be done in a methodologically sound manner. We do specify qualifications for EQROs and thereby believe that EQROs will have the skills necessary to perform qualitative and quantitative analysis of EQR-related information and draw proper conclusions. In addition, each EQRO must provide results as specified in § 438.364 that include a technical report specifying the objectives of, methods used, description of data obtained, and conclusions drawn from the EQR.

Comment: Many commenters were concerned that there has been no public review process for the protocols and that the meetings of the expert panel have been closed to the public. The commenters recommended that the public have the opportunity to review and comment on the draft protocols, that the protocols be issued annually, and the public have the opportunity to comment on any changes to the protocols. The commenters also stated that the protocols should be made publicly available on the CMS website. Several commenters asked that we provide an opportunity for interested parties and the public to comment on the protocols. They noted that providing the opportunity for all affected entities to review and provide comment on the protocols before they are finalized will allow for a better quality product and lend credibility to the protocols. One of the commenters further noted that even though CMS convened an expert panel to review the protocols as they were being developed, consumer participation was very limited.

Response: As stated earlier, on November 23, 2001, we published a notice in the **Federal Register** announcing the completion of the protocols and requesting comment on their burden or on any other aspect of the protocols. Comments on that notice and our responses to those comments are incorporated into this preamble. We will be publishing a notice in the **Federal Register** every 3 years on the protocols as required by the Paperwork Reduction Act. This notice will provide the opportunity for the public to comment on the burden or any other aspect of the protocols. The protocols are available to the public on the CMS Web site at *http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp.*

Comment: One commenter requested that in developing the protocols, JCAHO take into consideration that some factors that affect MCO performance are not within the control of the MCO, such as instability in eligibility status and changes in the characteristics of the enrolled Medicaid population.

Response: We agree that measuring performance on the Medicaid population needs to take into account issues such as changes in eligibility status. The protocol on performance measures recognizes those issues.

Comment: Because of the length of the protocols and the need to change them on an ongoing basis, one commenter requested that we clarify that the protocols be issued as guidelines rather than requirements and that we clarify the flexibility States will have in implementing them.

Response: Section 1932(c)(2)(A)(ii) of the BBA requires that protocols be used in the conduct of EQR activities. We provide States the option to use our protocols or protocols consistent with those we develop.

E. Qualifications of External Quality Review Organizations (§ 438.354)

Section 438.354 of the proposed rule set forth the requirements that an entity would be required to meet in order to qualify as an EQRO under the new BBA external review provisions in section 1932(c)(2) of the Act. The proposed rule did not specify categories of entities that would be qualified to perform EQR under section 1932(c)(2) of the Act. This is a departure from the existing external review requirement in section 1902(a)(30)(C) of the Act (which will no longer be in effect when these final regulations are implemented), under which only certain entities could perform external review. (These entities were: (1) A ''quality improvement organization'' (QIO) that contracts with Medicare to perform review (QIOs were formerly known as quality control peer review organizations, or ''PROs''); (2) an entity that meets the requirements to contract with Medicare as a QIO; and (3) a private accreditation body. Only contracts with the first two categories were eligible for a 75 percent matching rate under the pre-BBA rules.)

Under proposed § 438.354, in order to qualify, entities would be required to meet specified competence and independence standards. We proposed two tests of independence. Under the first proposed test, the EQRO and any subcontractors would have to be independent from the State Medicaid agency and from any MCO or PHP they review. Second, the relationship between the MCO/PHP and the EQRO could not involve any potential conflicts of interest. We specifically requested comments on (1) how better to identify situations that create conflict of interest; (2) the proposal to allow State entities to qualify as EQROs; and (3) our decision in the proposed rule to apply the ''independence'' requirement to subcontractors as well as contractors.

We also proposed that EQROs be selected by State agencies through an open, competitive procurement process. As noted in the preamble to the proposed rule, CMS would not, under our proposal, approve EQR contracts. However, contracts entered into by the States would be subject to review to ensure that, as a condition for FFP at the 75 percent rate, the State agency followed all applicable procedures and criteria. This proposed procedure is consistent with current practice, which is for State agencies to use competitive procurements to select EQROs that perform review under section 1902(a)(30)(C) of the Act. It is also standard practice for our regional office staff to monitor implementation of

Medicaid managed care initiatives. For EQR, regional office staff may review the State's most recent RFP for external review services, the EQR contract, or the EQR reports.

Comment: One commenter asked that a review of the current EQR process under section 1902(a)(30)(C) of the Act be performed by an independent review body to assist the Secretary in deciding whether current contractors are performing adequately.

Response: Section 1932(c)(2)(A)(ii) of the Act clearly instructed us, in consultation with States, to establish a method to identify entities qualified to conduct EQR. We chose to pursue a method that would allow States to have access to the greatest number of entities with the qualifications necessary to perform EQR and EQR-related activities. Therefore, we did not limit ourselves to a review of current contractors permitted to perform review under section 1902(a)(30)(C) of the Act, but attempted to discern all types of contractors that States have found capable of performing EQR-related activities. We believe this will provide States with much needed flexibility to promote greater competition and improvement among potential EQR contractors.

Comment: One commenter supported the provisions in the proposed rule that allowed for a variety of organizations to serve as an EQRO, but cautioned that EQRO criteria should include an unbiased approach to managed care. The commenter expressed concern that an anti-managed care organization could be awarded the contract, and that this would adversely affect the organization's ability to objectively make an assessment of MCO strengths and weaknesses and making recommendations for improvement.

Response: A State may contract with any entity to conduct EQR as long as the entity meets the competency and independence criteria. EQR is an important component of a State's quality strategy, and we trust that States will select entities to conduct EQR that will perform objective reviews.

Comment: Many commenters supported this provision because it provides States with more flexibility to contract with a range of organizations while still obtaining the 75 percent matching rate currently limited to contracts with QIOs, and entities that meet the requirements to contract as QIOs. Several of these commenters specifically supported the competence and independence standards proposed. One commenter agreed that the regulation should require organizational qualifications.

One commenter, however, found the requirements vaguely defined, and recommended that we stipulate additional requirements, such as proper licensure or certification from accrediting organizations for performance of validation of performance measures and surveys. Another commenter expressed concern that the proposed competency criteria would encourage the use of entities that are less qualified than the QIOs with which most States currently contract. The commenter believed that QIOs as nonprofit organizations, were independent, objective, and had access to needed physicians and experience in quality improvement. The commenter recommended that § 438.354(b)(1) be revised to read, ''require an organization to have staff with appropriate credentials and demonstrated experience.''

Response: The BBA required us to work in consultation with States to establish a method for the identification of entities qualified to conduct EQR. We believe that had the Congress desired to retain the three categories of entities allowed to perform EQR under section 1902(a)(30)(C) of the Act, it would have done so. Similarly, the Congress could have easily stated that only QIOs should perform EQR. The Congress chose neither of these approaches, but instead asked us to establish a method to identify qualified entities. We believe that the Congress chose to respond to States' frequently stated desires to have a greater range of organizations with which to contract. Therefore, under the auspices of the National Academy for State Health Policy (NASHP), we worked with States, consumer advocates, and other stakeholders to provide us with their recommendations on a methodology to identify qualified entities. Many commenters strongly supported the competency provisions we proposed under § 438.354(b). Therefore, the final rule retains these requirements from the proposed rule. We leave it up to States to determine if they would like to impose additional requirements such as certified vendors. We agree that demonstrated experience should be required of an EQRO, and in response to this comment, we have changed § 438.354 (b)(1) to require staff with demonstrated experience.

We also made some revisions to proposed § 438.354(a) to clarify that these provisions apply to those entities a State contracts with as an ''EQRO,'' regardless of whether the EQRO performs EQR or specific EQR-related activities.

Comment: One commenter felt that the proposed conflict of interest requirements failed to recognize that since the State contracts with the EQRO, the EQRO would be reluctant to tell the State what it may not want to hear. The commenter recommended having the EQRO funded by an external Federal agency, such as AHRQ (formerly AHCPR), or to require or create financial incentives to have the State report on comparable performance measures for all MCOs licensed in the State.

Response: Section 1932(c)(2) of the Act explicitly requires States that contract with Medicaid MCOs to provide for an EQR of each MCO, and provides for an enhanced Federal match rate for this review. We believe that it is clear that the Congress intended that States share the costs of EQR, and be the contracting party. We do not agree with the commenter's assumption that the State will not want to be informed if an MCO or PIHP is not performing adequately. We believe the provisions in this rule will encourage States to use EQROs to conduct numerous quality activities, both because of the flexibility that the rule provides to States, and because of the availability of the 75 percent enhanced match for these activities without regard to whether the entity performing review is a QIO or meets the requirements to contract as a QIO.

Comment: One commenter requested that EQROs be required to include clinical staff with pediatric training in order to be qualified to review a Medicaid MCO. One commenter recommended that the entity be required to have staff with knowledge of section 504 of the Rehabilitation Act of 1973, and of titles II and III of the ADA, based on the commenter's research suggesting that individuals who have mobility impairments routinely encounter physical barriers to care. The commenter's research also indicated that access to preventive care was significantly lower for individuals who use wheelchairs, and few PHPs know which of their clinicians are accessible to patients with mobility or sensory impairments.

Response: We do not agree that it is necessary to include specific requirements for EQROs to have clinical staff with pediatric training in order to qualify to review an MCO or PIHP. Section 438.354(b)(3) requires that the organization have the clinical skills necessary to carry out the EQR activity, which we believe requires that the EQRO or its subcontractor have the necessary training. We also do not agree with the commenter's suggestion that we specifically require an entity to have staff with knowledge of the Rehabilitation Act or the ADA. While

MCOs and PIPHs are required to comply with these laws, there are separate enforcement mechanisms for ensuring compliance with their provisions. We note that it is the responsibility of an EQRO to assess the MCO's or PIHP's ability to provide access to services in a timely manner. If this is accomplished for all enrollees, this would, in effect, constitute compliance with these laws. Through its review of compliance with State-established structural standards, as required in § 438.358(b)(3) of the final rule, the EQRO must ensure that Medicaid beneficiaries, including those who are disabled, do not encounter barriers to care.

Comment: One commenter suggested modifying proposed § 438.354(b)(1)(iii) to read ''* * * include quality assessment and improvement technologies and methods.''

Response: We agree with the commenter's suggestion that the word ''methods'' be used and believe that this term already encompasses technologies that may be employed by the State as a method for assessing and improving quality. Accordingly, in response to this comment, we are revising § 438.354(b)(1)(iii) to use the word ''methods.''

Comment: One commenter supported our proposal to allow State agencies to qualify as EQROs in certain situations. Another commenter believed it would also be appropriate for the State HMO licensing organization to be eligible to be an EQRO. Conversely, one commenter felt that EQROs should be independent of most State agencies, particularly Medicaid purchasing or managed care licensing authorities. Another commenter believed that it was extremely important that the definition of independence be explicit for State Medicaid agencies, and that CMS's regional offices should review determinations as to the independence to make sure that true independence is obtained. This was based on concern over what the commenter saw as an inherent conflict of interest permitted under our proposed rule. In the commenter's view, this conflict arises from the fact that State agencies, departments, and universities are ultimately accountable to State legislatures and the Governor who act on purchasing decisions made by the State Medicaid agency, and who appoint members to boards of these entities. One commenter expressed the view that no State agency is truly independent and recommended prohibiting State entities from serving as EQROs.

Response: Section 1932(c)(2) of the Act requires that a State contract with an independent organization in order to get the enhanced 75 percent FFP for EQR. The expert panel composed of State representatives, advocacy organizations, and other stakeholders that was convened under the auspices of the NASHP recommended that we allow State agencies to qualify under certain circumstances as EQROs. Because we agree with this recommendation and believe it to be reasonable with the safeguards on independence we have in place, the final rule retains the independence requirements that permit State Agencies under certain circumstances to qualify as EQROs. We note that we have received only a few comments opposing our proposal to let State entities qualify as EQROs. CMS regional office staff will assess the EQRO contracts to ensure compliance with the provisions of this rule as part of regular monitoring reviews.

Comment: One commenter did not agree with the requirement that a State entity be governed by a board or similar body, the majority of whose members are not government employees, in order to qualify as an EQRO. The commenter believed that State universities should be permitted to be EQROs because they can produce high quality work for significantly less cost than QIOs.

Response: We understand that the requirement will limit the number of State entities that can qualify as EQROs, including some State universities. We took this recommendation from the expert panel convened under the auspices of the NASHP. This panel included State licensure and Medicaid representatives. We are aware that several States have State entities that meet the criteria set forth in the proposed rule. We have received minimal comments opposing this provision. We conclude that this is a feasible arrangement, and think that the provisions related to the governing board are appropriate and necessary in order to fulfill a requirement for meaningful independence. We also believe it represents a reasonable compromise between banning State entities altogether, and allowing any entity to serve as an EQRO. Therefore, the final rule retains the governing board provision.

Comment: One commenter representing a Medicaid program not operating in the continental United States felt that the proposed independence criteria would have the effect of precluding all of its governmental procurement possibilities related to EQR. The commenter recommended that the independence criteria be waived, or that implementation be postponed, due to the financial burden the commenter believed that the rule would impose on it because it would have to contract with EQROs in the continental USA.

Response: The statute requires that the EQRO be an independent entity. Consistent with the interpretation of ''independence'' under the existing external review requirement in section 1902(a)(30)(C) of the Act, we interpret this to mean independent from both the MCO/PIHP and from the State. Thus, it is not clear how this final rule would create a financial burden by referring a contract with an outside entity, since this is already required. We do not agree that exceptions should be made based on a Medicaid program's ability to contract with an EQRO locally. We recognize that many State agencies, departments, and universities do not meet these criteria. However, as noted above, several States do have State entities that meet the independence criteria. We also note that this regulation provides more flexibility than in the past for a variety of organizations to qualify as EQROs.

Comment: One commenter disagreed with our proposal to apply the independence requirement to subcontracts, suggesting that this would result in States being unable to take advantage of the experience of nationally renowned experts affiliated with academic health centers that have ownership interests in MCOs that serve Medicaid beneficiaries. In contrast, one commenter endorsed applying independence criteria to EQRO subcontractors as balanced and reasonable.

Response: The independence provisions are broad enough to allow for a variety of organizations to qualify as EQROs and a variety of experts to subcontract with EQROs. In formulating the provisions, we sought balance between providing flexibility to States to choose from numerous qualified entities, and ensuring that entities were sufficiently independent from the State and the MCOs and PIHPs. We realize these requirements will limit some contracting opportunities when experts or the organizations for which they work do not meet the independence criteria.

Comment: Many commenters agreed with the expert panel recommendation that the EQRO should not share management or corporate board membership with the MCO it reviews. The commenters also suggested that the individuals employed by the EQRO or subcontracting with the EQRO should be free of any potential conflicts of interest with the MCO that they review.

Response: In the preamble of the proposed rule, we explained that we did not solely rely upon the recommendation that an EQRO should not share management or corporate board membership with the MCO it reviews, because we do not think this criterion is stringent enough to ensure against conflict of interest. Therefore, we incorporated in § 438.354(c)(3)(i), the concepts of ''control'' in 48 CFR 19.101, which effectively preclude affiliation between the EQRO and the MCO/PIHP under review. Specifically, this means that there can be no control through common management (which includes interlocking management, common facilities, and newly organized concerns) as well as through stock ownership, stock options and convertible debentures, voting trusts, and contractual relationships (which includes joint ventures, that is, procurement and property sale assistance and franchise and license agreements). We retain this provision in our final rule. In order to provide further clarification in § 438.354(c)(3)(i) of the final rule (§ 438.354(c)(3) of the proposed rule), we now specify the different types of control addressed in § 19.101. In determining whether this type of control exists, the details in § 19.101 under each category would apply.

Comment: Several commenters recommended strengthening the requirements for EQRO independence from MCOs by revising § 438.354(c)(3) to read as follows: ''A private entity may not (1) have managed care licensing authority, including the authority to certify managed care plans in compliance with standards that serve as the basis for deemed certification with Federal or State regulatory standards; (2) deliver any health care or related services to Medicaid recipients for which it is paid by the Medicaid State agency or by a managed care plan. Related services include enrollment services, grievance resolution, external review of health care coverage decisions, or other similar activities; (3) conduct, on the State's behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services; and (4) have financial interest that would prevent it from exercising independent judgement when engaging in EQRO activities.'' The commenters also suggested adding a new § 438.354(c)(4) providing that ''a private entity must be governed by a board or similar body, the majority of whose members are not MCO employees.'' Another commenter did not agree with the provision that prohibits an organization from performing EQR if it also conducts ongoing Medicaid program operations related to quality, arguing it could be less expensive to use a single contractor to perform multiple functions. One of the commenters found the definition of control in 48 CFR 19.101 a useful concept, but felt that it has little relevance to the potential organizational relationships between EQROs and MCOs in the Medicaid program.

Response: The independence criteria set forth in the proposed rule did not address those private organizations that provide health care services to Medicaid beneficiaries or that conduct ongoing Medicaid program operations related to quality. We agree with the commenters that organizations performing these functions have a conflict of interest. Therefore, in response to this comment, we are revising § 438.354(c)(3)(ii) in this final rule to preclude private organizations, as well as State entities, that provide health care services to Medicaid beneficiaries from qualifying as EQROs. We also are revising § 438.354(c)(3)(iii) to preclude private organizations as well as State entities, that conduct ongoing Medicaid managed care operations related to quality from qualifying as EQROs. We narrow the scope of this provision from entities that conduct program operations to entities that conduct managed care related operations in order to allow States to contract with entities that conduct quality activities for the States such as FFS medical and utilization review activities. We agree with the last commenter who agrees that it will be more efficient for States to use a single contractor to perform multiple functions; therefore, we intend to allow entities that conduct limited quality activities such as providing technical assistance to States in the collection of encounter data or who assist the State in other quality improvement areas to qualify as an EQRO. These activities would not be considered ongoing operations conducted on behalf of the State.

We do not permit an entity to qualify as an EQRO if that entity conducts activities that State staff would otherwise conduct in Medicaid managed care program operations related to quality oversight. As an example, a State university or consulting firm that designs and implements or has significant responsibility for the State's Medicaid managed care program operations would not qualify as independent.

We do not agree with the commenter who recommended that the independence provisions should preclude any organization from being an EQRO that has the authority to certify managed care plans in compliance with standards that serve as the basis for deemed certification with Federal or State regulatory standards. These organizations, while they may provide services under contract to a State, follow their own independently set standards and procedures. We believe that States should be permitted to contract with these organizations to consolidate review processes. This is consistent with congressional intent as indicated by the nonduplication and deemed compliance provisions in sections 1932(c)(2)(B) and (C) of the Act.

As stated above, we agree with the commenters' suggestions to revise the independence criteria as it applies to private organizations that deliver health care services to Medicaid beneficiaries or who, on behalf of the State, conduct Medicaid managed care program operations related to quality. However, we do not agree with the commenters' suggestions to add to this provision health care-related services such as enrollment services, grievance resolution, and review of health care coverage decisions. We leave it to the States to determine if health care-related services are Medicaid managed care program operations related to quality, in which case the organizations would be precluded from qualifying as an EQRO. In addition, States have the flexibility to adopt a more strict standard for ''independence'' if they wish and to deny entities that provide any health care-related services from contracting as an EQRO.

We agree with the commenters' suggestions that the final regulation include a provision to prohibit an EQRO from having a financial interest that would prevent it from exercising independent judgement when engaging in EQRO activities. The types of ''control'' addressed in 48 CFR 19.101 address financial relationships involving such things as stock options and convertible debentures. To be consistent with other CMS regulations, however, and in order to respond to this comment, we believe the financial relationship between organizations must be addressed in the conflict of interest requirements. Therefore, we revised § 438.354(c)(3)(iv) to address direct and indirect financial relationships. We also have added a definition for financial relationships under § 438.320.

We believe the language in proposed § 438.354(c)(2) addresses the suggestion by one commenter that we add a provision requiring a private entity to be governed by a board or similar body, the majority of whose members are not

MCO employees. By referencing 48 CFR 19.101, specifically § 19.101(f)(1), a concern is considered controlling through interlocking management if officers, directors, employees, or principal stockholders serve as a working majority of the board of directors or officers of another concern. As noted above, to provide clarification, the final rule under § 438.354(c)(3)(i) (§ 438.354(c)(3) of the proposed rule) specifies the elements that constitute control of one entity over another as those in 48 CFR 19.101.

Comment: Several commenters expressed support for our independence requirements. One commenter supported our proposal to allow States to contract with entities that possess the necessary skill and expertise to conduct the mandatory and optional EQR activities, but suggested that we query State agencies for specific citations or contract language that they have used to define independence, or for concrete examples of situations that may create conflicts of interest. The commenter also suggested that we consider delineating specific competence standards for each of the mandatory activities. One commenter agreed that it is critical for CMS to establish a set of criteria to which States must adhere when selecting EQROs.

Response: At the expert panel meeting convened under the auspices of the NASHP, we asked the panel for recommendations on how to define conflict of interest. This panel included State representatives as well as representatives from advocacy organizations and other stakeholders. The expert panel recommended that independence be established by requiring the disclosure of any ownership interest of greater than 5 percent of the entity seeking to become an EQRO. As was discussed in the proposed rule, we believe this ''disclosure of ownership'' requirement is inadequate to ensure independence, first, because is does not preclude an entity from being an EQRO but only requires disclosure of the financial interest, and second, because there may be other types of conflicts such as interlocking management, common facilities, and so forth. Moreover, in the proposed rule, we requested comments on how better to identify situations that create conflict of interest. As noted above, we made some changes based on comments we received.

We do not believe that it is necessary for us to revise the competency requirements to address each EQR activity. The criteria outlined in the proposed rule were intentionally broad to provide States with the flexibility to contract with one or multiple entities that have the skills necessary to conduct the particular activity/activities under contract. For example, if a State wants to have one of its EQROs conduct only encounter data validation, to meet the requirement under § 438.354(b)(3), the EQRO would not need to possess the clinical skills but would need the ''nonclinical skills'' in its organization (or through a subcontract) to conduct encounter validation.

Comment: A commenter believed that the proposed rule did not make clear who, specifically, would be responsible for designating an entity as an EQRO. The commenter recommended that this responsibility rest in our Office of Clinical Standards and Quality, as it already has oversight responsibility for Medicare's Health Care Quality Program.

Response: Under this rule, States are required to select and thereby designate EQROs through an open, competitive procurement process. CMS will not be designating EQROs, as it currently does in the case of QIOs and entities claiming that they meet the standards to contract as a QIO. When monitoring State Medicaid managed care programs, CMS regional office staff have the opportunity to review RFPs, contracts, and EQR results to ensure compliance with the EQR provisions.

F. State Contract Options (§ 438.356)

This section set forth proposed requirements State agencies would be required to follow, and options that they would have selecting EQROs. We proposed that State agencies may contract with more than one EQRO. The final rule in § 438.356 (a)(1) and (a)(2) reflects clarifications made to the provisions based on comments discussed in an earlier section of the preamble.

We also proposed that each EQRO be permitted to use subcontractors. EQROs that use subcontractors are accountable for, and required to oversee, all EQR activities performed by the subcontractors. In addition, we proposed that each EQRO be required to meet the competency requirements, and each EQRO and EQRO subcontractor be required to meet the independence requirement. We also proposed that State agencies follow an open competitive procurement process that is in accordance with State law and regulation and consistent with 45 CFR part 74, as it applies to State procurement of Medicaid services.

Comment: Several commenters supported the language in § 438.356 as proposed. One commenter specifically agreed that all subcontractors should be required to meet the test of independence, and that the contract must be procured through a competitive bid process.

Response: We appreciate the commenter's support for the provisions, and have retained them in the final rule.

Comment: One commenter believed that a competitive bidding process was the most appropriate way for States to secure efficient cost-effective reviews.

Response: We agree that competitive bidding provides the best means to select a qualified contractor at the best price, and we retain the requirement for competitive procurement of EQROs in the final rule.

Comment: One commenter asked us to clarify whether the State Medicaid agency could contract directly with a State organization without using a competitive procurement process if the State organization otherwise meets the standard of being ''independent,'' and meets the requirements of a qualified EQR.

Response: The Department of Health and Human Services has regulations governing the extent to which States are required to competitively procure contracts. Those regulations apply to EQRO contract as cited under § 438.356(e).

G. Activities Related to External Quality Review (§ 438.358)

Section 438.358 proposed a requirement that EQR utilize information obtained from specified mandatory activities that must be performed by the State agency, a State agent, or the EQRO. Proposed § 438.358 also identified optional activities that the State agency or its agent may perform, or have the EQRO perform, to produce additional information for use in EQR. The mandatory activities are consistent with the requirements set forth in the Medicaid managed care final rule. The optional activities were not included in that rule. They are, however, activities that States have had their EQR contractors perform in the past.

We proposed that each year, the EQRO must use information obtained from the validation of performance improvement projects performed that year, and the validation of performance measures reported that year, by the MCO. To be consistent with the private sector, however, we proposed that information used by the EQRO from a review of MCO and PHP compliance with State structural and operational standards be from the most recent review performed within the previous 3 years.

Proposed § 438.358 also would allow States to have their EQROs provide technical guidance to groups of MCOs and PHPs to assist them in conducting the mandatory and optional EQR-related activities.

Comment: One commenter requested that States be required to provide technical support to MCOs to ensure that pediatric measures are implemented. The commenter also expressed a concern that the proposed EQR regulations did not separately address children with special health care needs, noting that it was critical that CMS require State Medicaid managed care programs to provide adequate protections and considerations for these children.

Response: States have the flexibility to provide technical support to MCOs and PIHPs on pediatric measures as well as generic measures, preventive care measures, measures for disabled adults, or any other measures. This rule does not require this technical support, however, because we do not believe that it would be necessary in all cases.

With respect to special needs children, this regulation implements the BBA EQR provisions by specifying who is qualified to conduct EQR and what information should be included in such a review. The Medicaid managed care final rule requires States to have quality strategies that must include procedures that assess the quality and appropriateness of services provided to all Medicaid enrollees under MCO and PIHP contracts. This includes children with special health care needs. The EQR will evaluate activities undertaken by MCOs and PIHPs in accordance with the State strategies. States can elect to have their MCOs and PIHPs determine what measures to collect or States can require MCOs and PIHPs to collect specified measures appropriate to the populations served.

Comment: One commenter strongly recommended that these regulations mandate that States require MCOs to develop and administer a provider satisfaction survey. The commenter thought this would allow the MCOs to use the results of the surveys to identify additional approaches to enhance quality of care. It also would allow States to identify MCOs that may be poised to experience a rapid withdrawal of providers, which could place beneficiaries at risk of having difficulty accessing care, or otherwise disrupt their medical home. Another commenter felt that the validation of consumer or provider surveys would be difficult. This commenter asked whether we were proposing that EQROs contact respondents to ask them if the answers that were recorded were the answers given.

Response: This rule does not require that States have their MCOs and PIHPs develop or administer consumer or provider surveys. It does, however, allow States to have their EQRO administer or validate a consumer or provider survey, and receive the 75 percent enhanced match for this activity as long as the EQR survey protocol or a consistent protocol to the one we developed is used. The EQR survey protocol does not require that respondents be contacted to validate survey responses. We agree that this would be costly and burdensome. The survey protocols outlines generic steps that must be followed to ensure reliable and valid methodological approaches to administer and validate surveys.

Comment: One commenter recommended that we require that EQROs measure and report the participation of pediatricians, pediatric medical subspecialists, and pediatric surgical specialists when conducting activities related to the establishment of provider networks.

Response: EQRO reviews for compliance with structural and operational standards will include a review of the delivery network. The review will ensure, consistent with the Medicaid managed care final rule, that MCOs and PIHPs maintain and monitor a network of appropriate providers to furnish services covered under the contract and that they consider the anticipated Medicaid enrollment with particular attention to the needs of enrolled children; the expected utilization of services; and the geographic location of providers and enrollees. When developing and maintaining their provider network, MCOs and PIHPs will also need to consider the characteristics and health care needs of enrollees.

Comment: One commenter believed that while it arguably was reasonable to require external auditing of broad, publicly disclosed quality performance measures, the same mandate should not be imposed on other quality improvement data such as the findings of focused clinical studies. In this commenter's view, these types of data are intended to promote MCO self-assessment and stimulate quality improvement activities, and should not be subject to an external audit.

Response: We do not agree with the commenter that the findings of focused studies or other quality improvement projects should not be subject to an EQR. Our Medicaid managed care final rule requires MCOs and PIHPs that contract with States to provide Medicaid services to conduct performance improvement projects, calculate performance measures, and comply with structural and operational standards. In order to ensure compliance with these requirements, we believe a review of all these activities is essential to determine the quality, timeliness, and access to services provided to Medicaid beneficiaries. However, § 438.364 requires that only the aggregated findings of the EQRO analysis of all information derived from the EQR activities be produced, and it is only this summary information that is to be made available to the public upon request.

Comment: One commenter believed that it was vital to include in EQR a range of activities beyond ''focused studies'' and medical record review. This commenter felt that the mandatory activities proposed would require the collection and use of data from multiple sources, and that we may want to consider mandating the validation of primary data sources such as encounter data and survey data. Another commenter asked that focused studies be a mandatory activity, and that MCOs be required to show measurable improvement in them. One commenter supported our establishing mandatory activities as well as the optional activities that are eligible for the 75 percent matching rate.

Response: We are aware of the importance of the integrity of the MCO's and PIHP's underlying information systems for the conduct of some EQR activities, and we address this issue in the protocols for review for compliance with structural and operational standards, performance measures, and encounter data. We do not include focused studies as one of the mandatory activities in this regulation because the Medicaid managed care final rule requires that MCOs and PIHPs conduct performance improvement projects. A performance improvement project begins with a focused study to select a clinical or nonclinical topic and measure performance in that area, but takes steps beyond a focused study to implement activities to improve performance. This regulation requires that the State include information regarding the validation of these studies as part of EQR.

Comment: Several commenters were concerned that this rule potentially would permit EQROs to analyze and evaluate data collected by a party not subject to the same conflict of interest requirements as the EQRO. These commenters were concerned that the EQRO would be held accountable for the validity, accuracy, and reliability of

the MCOs' projects without necessarily having access to the raw data. One of the commenters suggested that there be continued discussions with the QIO community about the need for raw data files from MCOs in order to evaluate the performance improvement projects and performance measures. The commenter also felt that EQR performance measures should be standardized and consistent to allow comparisons among the States, and among the MCOs operating in more than one State. Another commenter recommended that the final rule require that EQR activities be carried out by the EQRO. If the information provided for the EQR is collected by the State or another agency, the commenter suggested that the EQRO be required to validate the data or information before analyzing it or forming conclusions about quality, timeliness, and access.

Response: In order to receive the enhanced 75 percent Federal match provided for in section 1903(a)(3)(C)(ii) of the Act, we believe most States will use an EQRO to conduct the mandatory EQR-related activities. However, in order to provide flexibility to States to coordinate their quality oversight activities, we permit States or their agents to perform the mandatory EQR activities, and only require that States use an EQRO for the conduct of EQR (as defined under § 438.320) and for the production of the EQR results as specified under § 438.364. If a State chooses not to have an EQRO conduct the mandatory activities, the State still needs to use, or have its contractor use, our protocols or protocols that are consistent with ours when conducting these activities. The State will also need to provide the EQRO with the information specified under § 438.364(a)(1)(i) through paragraph (iv) for each of the EQR-related activities as required in § 438.350(b). We believe this last requirement may not have been clear in our proposed rule, and we have therefore provided a cross-reference to § 438.364(a)(1)(i) through paragraph (iv) in § 438.350(d) in this final rule. This clarification addresses the comments above by identifying the types of information we expect to be provided to an EQRO if the State or a contractor other than the EQRO is conducting the EQR-related activity. We also provide clarifying language in a new § 438.358(a) of this final rule, which sets forth a general rule making clear that a State can conduct, or have another State contractor or the EQRO conduct, the mandatory and optional EQR-related activities that provide information for the EQR function.

We do not agree that the EQRO must revalidate activities already validated by the State or another State contractor that uses our protocols. We believe the use of the protocols will ensure that each of the activities, including an assessment of the underlying data systems, is conducted using reliable and valid methods.

We are not requiring standardized performance measures. In our Medicaid managed care final rule, we require States to require MCOs and PIHPs to use standard measures. The Medicaid managed care final rule also gives CMS the authority to prescribe standard measures in consultation with States and other stakeholders. Currently, States have the flexibility to determine which measures they will require of their MCOs and PIHPs. The CMS protocol for performance measures sets out a standard method to validate performance measures. We have also developed a protocol for calculating performance measures, as this is an optional EQR-related activity.

Comment: One commenter believed that allowing the use of information obtained by the State or its agent for EQR means the information is not truly independent. The commenter further contended that the methods used by the State or its agent do not have to be consistent with the EQR protocols, since the State or its agent is not an EQRO.

Response: Consistent with provisions at § 438.350(b) and (c), whoever conducts the mandatory or optional EQR-related activities must use the protocols or methods consistent with the protocols. We have made this clear in the final rule.

Comment: Several commenters noted that the activities under § 438.358 are currently in some cases conducted by the State, the county, or both. They added that having the EQRO perform this same activity, or even review these activities would be redundant and costly. One of these commenters suggested that we allow these activities to be done directly through the State or county survey process.

Response: EQR-related activities may be conducted by the State or by any State contractor other than the MCO or PIHP as long as the activities are conducted consistent with our protocols. However, if a State chooses to have its EQRO conduct these activities it can obtain the enhanced 75 percent Federal match under section 1903(a)(3)(C)(ii) of the Act.

Comment: One commenter asked that we clarify whether information derived from optional activities performed by other fiscal government agencies could be used by the EQRO.

Response: As long as the other agency uses our protocols or methods consistent with the protocols, the information derived from EQR-related activities performed by other State agencies can be used as part of EQR. The State, however, would not be able to receive the enhanced 75 percent Federal match unless the other government agency qualified as an EQRO, and the contract to conduct the activities was procured consistent with § 438.356(e). We clarify in this final rule that the information obtained from optional EQR-related activities must be from information derived from optional activities conducted within the preceding 12 months.

Comment: Several commenters believed that MCOs should be required to report on standardized performance measures for specific conditions. One of these commenters also recommended that MCOs be required to report on aggregate measures of changes in health status for all people who meet a definition of disability. The commenter further urged that the development of these measures be a priority for both quality assurance and reimbursement purposes.

Response: As stated previously, the Medicaid managed care final rule provides States with the authority to specify what performance measures to require their MCOs and PIHPs to calculate and report. We are allowing this flexibility because State Medicaid managed care programs differ in the services they contract for and the populations served by MCOs and PIHPs. We think it is important that States be able to make comparisons across their contracting MCOs and PIHPs and, where this information is available, we require that it be provided as part of the EQR results as specified in § 438.364(a)(4). However, while the Medicaid managed care final rule provides CMS with the ability to prescribe performance measures in consultation with States and other stakeholders, at this time we are not requiring the collection of comparative data nationwide.

We are also not requiring that States collect health status information from their MCOs and PIHPs. States are free to do this if they choose, and an increasing number of States are assessing the health status of MCO and PIHP enrollees for purposes of risk adjusting payments, or for quality activities. This rule also allows States to have their EQRO administer consumer surveys and obtain an enhanced Federal match of 75 percent. Approximately 30 States currently administer consumer surveys, primarily the CAHPS survey, which collects health status information from the perspective of consumers.

Comment: One commenter felt that the EQR-related activities were not clearly defined, and were limited in scope. The proposed language did not appear to the commenter to require the State to provide actual data to the EQRO, only information on the validation of the data. The commenter was concerned that the State could report to the EQRO that the data are valid, without actually providing the data itself.

Response: We do not agree with the commenter that the EQR-related activities are limited in scope. The activities reflect those that States have used existing EQR contractors to conduct in the past. These activities are more fully explained in the protocols that we reference in this final rule. On November 23, 2001, we published a notice in the **Federal Register** announcing the completion of these protocols noting their availability on our website and asking for comment on the extent to which they impose a burden, as well as any other issues the commenters wished to raise. Our protocols clearly define EQR activities, and the steps needed to conduct these activities in a valid and reliable manner. As noted in the preamble of our proposed rule, the full content of the protocols themselves was not included in the proposed rule, and is not included in this final rule because the protocols are more detailed than appropriate for Federal regulations, will need to be revised as the state-of-the-art of quality improvement changes, and States may use other protocols as long as they are consistent with those we developed. The need for the EQRO to have raw data will depend on the activities a State chooses to have its EQRO perform. For the actual conduct of EQR as defined in § 438.320, as well as the mandatory activities, access to raw data will not be needed. If the EQRO conducts all of the mandatory activities, it will be responsible for validating the methodological approach used by the MCO and PIHP for the conduct of performance improvement projects, and the calculation of performance measures. Regardless of who conducts the EQR-related activities, the CMS protocols, or a method consistent with the CMS protocols, must be used, and the information derived from the activity, as specified in § 438.364(a)(1)(i) through paragraph (iv), must then be provided to the EQRO.

Comment: One commenter did not support our decision to make performance improvement projects a mandatory activity, while focused studies are an optional activity. The commenter expressed concern that performance measures tend to focus on things that are easy to fix, and do not always provide a reliable picture of quality across a broad range of concerns.

Response: As the state-of-the-art of quality assessment and improvement has changed, we have found it more suitable to implement performance improvement projects than focused studies. Focused studies aim to assess the quality of care provided at a point in time, whereas performance improvement projects, in addition to assessing a focused area of care at a point in time, aim to initiate an intervention to improve care over time. In our proposed rule, we discussed the limitations of solely using focused studies, without information from other quality activities, to assess the care provided to all enrollees of a State Medicaid managed care program. It is for these reasons that improvement projects are mandatory while focused studies are optional. We note, however, that States may employ focused studies and use an EQRO to conduct this activity, thus accessing the enhanced 75 percent Federal match under section 1903(a)(3)(C)(ii) of the Act.

In this rule, we provide for a multipronged approach to quality improvement that uses information from three sources: (1) Determination of compliance with standards, (2) validation of performance improvement projects, and (3) validation of performance measures. We believe that this approach will provide for a reliable assessment of the quality, timeliness, and access to care provided to Medicaid beneficiaries by an MCO/PIHP.

Comment: One commenter interpreted the proposed rule to prohibit States and EQROs from conducting focused studies, and to instead require States to perform comprehensive reviews of all areas of the MCO contracts every year. This commenter recommended that we reconsider the scope of annual review, suggesting that a 1 year cycle does not allow sufficient time to procure an EQR contract, conduct and complete EQR activities, and report results on the EQR as specified in this rule. The commenter also recommended that we allow for a multiyear rotational approach to quality measurement and improvement (for example, rotate specified performance measures, focused clinical topic reviews). One commenter similarly believed that 1 year was too short a period of time in which to conduct the activities under § 438.358 (a)(1)(i) and (ii) of the proposed rule. This commenter suggested that this time period instead be left up to the State agency. Another commenter recommended that we require only that the information used by the EQRO for validation of performance improvement projects be from the most recent review performed within the previous 3 years, rather than requiring a yearly review.

Response: Section 1932(c)(2) of the Act requires an annual external review. In the final rule, we require that there be three sources of information used in this review. First, for performance improvement projects, this final rule requires that there be performance improvement projects underway during the previous 12 months. We understand that an MCO or PIHP may have multiple projects underway at a given time, and these projects may be at various stages of implementation. In response to this comment, we have revised the language under proposed § 438.358(a)(1)(i) (now § 438.358(b)(1)) to clarify that performance improvement projects need to be underway during the preceding 12 months, instead of having been completely performed during the preceding 12 months. Consistent with private sector practices, we therefore would allow States to use a multiyear rotational approach when conducting performance improvement projects and calculating performance measures. Second, for performance measures, the rule requires that one or more measures be reported annually. Finally, as was indicated in our proposed rule, EQR also needs to employ information from a review of structural and operational standards, conducted within the previous 3-year period.

Comment: Many commenters suggested that the list of mandatory activities include an examination of reasons for disenrollment and termination.

Response: Under § 438.358(b)(3) of this final rule, we require a review of MCO and PIHP compliance with State standards, in accordance with the Medicaid managed care final rule. This includes standards for enrollment and disenrollment. The Medicaid managed care final rule includes standards for disenrollments requested by the beneficiary, as well as those requested by the MCO or PIHP. In addition, the Medicaid managed care final rule requires MCO and PIHP compliance with State standards for health information systems. As part of the health system provisions, we require that the State ensure that the MCO or PIHP information system provides information including, but not limited to, utilization rates, grievances, and numbers of appeals and disenrollments. We believe these provisions adequately address the commenter's concern, and

that no additional requirements are necessary.

Comment: One commenter noted that there was no cross-reference in the proposed EQR rule to the requirements in the then proposed Medicaid managed care rule that required MCOs to measure performance and conduct performance projects, and to comply with State-mandated standards. The commenter suggested that we make this cross-reference to the applicable sections in the Medicaid managed care rule.

Response: We have in this final rule added cross-references to the appropriate citations in the Medicaid managed care final rule.

Comment: One commenter recommended that we establish a core set of State standards for MCOs and evaluate these during the EQR process. The commenter was concerned that allowing States to determine the measures to be collected would provide little or no comparable plan or State level data.

Response: We do not agree that this rule should specify standardized performance measures for States or their contracting MCOs and PIHPs. The Medicaid managed care final rule specifies that States, through their contracts, must require their MCOs and PIHPs to calculate performance measures or submit data to the State that enables the State to measure MCO's or PIHP's performance. Many States currently require that standard performance measures be collected across MCOs. In addition, we believe that States will require that specified measures be calculated over time to enable the State to evaluate MCO and PIHP performance. In § 438.364(a)(4), we require that the EQR results include comparative information, as determined appropriate by the State. Furthermore, § 438.10(i)(2)(ii) of the Medicaid managed care final rule requires, for those States that provide for mandatory managed care under section 1932(a)(1)(A) of the Act, that the State provide comparative information annually. This must include, to the extent available, quality and performance indicators as required under § 438.10(i)(3)(iv). In addition, the Medicaid managed care final rule provides that CMS may, in collaboration with States and other stakeholders, prescribe standard performance measures.

Comment: One commenter asked us to clarify how proposed § 438.358(a)(1) fulfills the statutory requirement of EQR, and specifically how this information relates to a review of ''the quality outcomes and timeliness of, and access to, the items and services for which the managed care organization is responsible under the contract.''

Response: In order to make an assessment about the quality, timeliness, and access to services provided by MCOs and PIHPs, there must be information from which an assessment can be made. Section 1932(c)(A)(iii) of the Act required us, in coordination with the NGA, to contract with an independent quality review organization to develop protocols to be used in EQR. In order to develop protocols, we first needed to define EQR, as it was not defined under section 1902(a)(30)(C) of the Act. We also needed to determine what activities we consider necessary or appropriate to provide information for a quality review. The EQR activities in § 438.358(b) and (c) are activities that (1) the expert panel convened under the auspices of the NASHP recommended be included as part of EQR; (2) a survey of States by the Department of Health and Human Services' Office of Inspector General identified as quality review activities used by States; and (3) a survey of States by NASHP confirmed as activities most frequently used by States for EQR. The EQRO must develop a report, based on the information provided, as specified in § 438.364, that includes a detailed assessment of each MCO's and PIHP's strength and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

Comment: A commenter noted that the rule does not clearly identify which entities are qualified and competent to undertake the validation of performance measures and performance improvement projects. In the commenter's view, as drafted, the rule could be interpreted as allowing entities other than EQROs, including the State or the MCO itself, to undertake these tasks. The commenter recommended that we clarify what types of entities can engage in validation activities and at a minimum require those entities to be competent and independent.

Response: The State, an EQRO, or other State contractor can undertake any of the EQR-related activities. However, it is only when an EQRO, that meets the competency and independence criteria, conducts any of these activities that a State can obtain the enhanced 75 percent Federal match under section 1903(a)(3)(C)(ii) of the Act. Regardless of who conducts the activity, the CMS protocols (or other protocols consistent with ours) must be used to gather information for the mandatory and optional activities used in EQR. We did not intend to allow the MCO or PIHP itself to be able to conduct any EQR-related activities and in response to this comment we have revised § 438.358 so that it is clear that ''the agent'' must be an entity other than an MCO or PIHP.

Comment: One commenter recommended that we modify the regulation to grant State agencies the discretion to adapt these requirements to more appropriately address the circumstances of small or new MCOs and PHPs. The commenter suggested that enrollment in some MCOs and PHPs may be too small for an EQRO to validate the data for performance improvement projects or performance measures. Similarly, for an MCO that is not yet operational or which has only been operating for a short amount of time, there may be insufficient experience to use to evaluate for compliance with standards.

Response: We do not agree that we should modify the regulation to allow States to adapt the requirements to address small or new MCOs and PIHPs. If enrollment in an MCO or PIHP is small, the entire applicable population, as opposed to a sample, can be used when conducting performance improvement projects, calculating performance measures, or validating these activities. Regarding compliance with State standards, all MCOs and PIHPs that contract with a State to provide Medicaid services must be in compliance with the contracting requirements in the Medicaid managed care final rule. Regardless of when the EQR is conducted, MCOs and PIHPs should have procedures in place to be compliant with these provisions. Therefore, an assessment of compliance with these standards must be conducted and the findings provided to the EQRO to make its assessment regarding quality, timeliness, and access to services provided by the MCO or PIHP to Medicaid beneficiaries.

Comment: One commenter felt that State Medicaid agency staff should conduct the review of MCO compliance with structural and operational standards, as the review requires extensive knowledge of the State Medicaid program, its regulations, and the MCO contract. This commenter believed that this requirement was duplicative of current practice and unnecessarily burdensome, and did not provide States needed flexibility to choose which activities it wants to have its EQRO conduct. The commenter suggested deleting this provision. Another commenter urged that the review of compliance with standards be an optional instead of mandatory activity. The commenter noted that States conduct this activity through

various means, and that mandating this be done through EQR would mean an increase in Federal and State funding for the EQR contract. One commenter believed that the proposed requirement for review of structural and operational standards went beyond the statute's reference to ''quality outcomes, and timeliness of, and access to items and services for which the organization is responsible under contract.'' This commenter recommended that we reevaluate the extent of this review to ensure that it is consistent with the intent of the statute. The commenter further noted that this review was so broad that it would encompass most of the areas currently reviewed by States under their general contract responsibilities.

Response: States are not required to contract with an EQRO to conduct a review of the MCO's or PIHP's compliance with State structural and operational standards. A State can conduct this activity using the CMS protocols or protocols consistent with ours and provide the results of the review to the EQRO. The regular 50 percent administrative FFP match would be available to the State for this activity if it is not conducted by the EQRO. The EQRO will use this information in conjunction with information derived from the other two mandatory activities and any optional EQR-related activities conducted to determine quality of, timeliness of, and access to the quality of care provided by the MCO or PIHP. This final rule provides States with the flexibility to determine which activities it wants to have its EQRO conduct. Although we prescribe mandatory activities, which are consistent with the requirements set forth in the Medicaid managed care final rule, the State does not have to have its EQRO conduct these activities. A State is only required to have an EQRO conduct the analysis and evaluation of the information derived from the activities to determine if an MCO or PIHP is providing access to quality services. We do not believe that the scope of the mandatory activities goes beyond the statutory provisions under section 1932(c) of the Act which require States to have a quality assessment and improvement strategy which includes access standards, and measures to assess care, including grievance procedures and marketing and information standards. Furthermore, the statute requires that States implement monitoring strategies that address the quality and appropriateness of care. We, therefore, retain the review of MCO and PIHP compliance with State standards as a mandatory activity in our final rule.

Comment: One commenter believed that the intent and usefulness of the proposed language in § 438.358 requiring the EQR to ''use information'' obtained from the mandatory and optional EQR-related activities was unclear. The commenter recommended changing the language to read ''The State or the EQRO shall/must conduct'' the EQR-related activities.

Response: Sections 1932(c)(2)(A)(ii) and (iii) of the Act required us to (1) in consultation with States, develop a method to identify qualified entities for the conduct of EQR, and (2) in coordination with the NGA, develop protocols to be used in EQR. In order for us to determine who was qualified to conduct EQR and for us to develop protocols to be used in an EQR we first needed to define EQR. Based on the advice of an expert panel convened under the auspices of the NASHP, the proposed rule, and this final rule, define EQR as the analysis and evaluation by an EQRO of aggregated information. Based on this definition, the expert panel confirmed the types of activities that would produce information as it relates to the quality, timeliness of, and access to care provided to our beneficiaries. These are the mandatory and optional activities found in this section of our rule. To provide consistency with the definition of EQR, and because we do not require that States contract with an EQRO to conduct these activities, we retain the language that an EQR must use information derived from the EQR-related activities in the final rule.

Comment: Many commenters did not agree with our proposal to require that information be used from a review of structural standards every 3 years, and cited the statutory language requiring ''an annual * * *'' review. Many commenters recommended that all activities be done annually, citing reasons such as the changing status of provider networks, and pressures to control utilization. One commenter claimed that we did not adequately explain our rationale for permitting the use of data and information that may be up to 3 years old. The commenter argued that given the volatility of both the managed care market place and State Medicaid programs, the problems identified in Medicaid managed care systems throughout the country, and the fact that the majority of beneficiaries are children, allowing the use of 3-year-old data was inadequate. The commenter suggested that an evaluation of quality, timeliness, and access to services must be timely to allow for effective interventions to correct the problems.

Response: Reviews of MCO and PIHP compliance with structural and operational standards are very time consuming and costly. To be consistent with private industry standards, we proposed that information from the review of MCO and PIHP compliance with standards be from the most recent review conducted within the previous 3 years. Both NCQA and JCAHO perform their accreditation reviews once every 3 years. As stated earlier, our rule takes a multipronged approach to quality assessment and improvement. This is one reason why we require the EQR to use information from a minimum of the three mandatory activities to render a decision regarding the quality and timeliness of and beneficiary access to health care services. We believe that this comprehensive approach addresses the commenters' concerns, and that annual reviews for compliance with structural standards is not justified.

H. Nonduplication of Mandatory Activities (§ 438.360)

Proposed § 438.360 provided State agencies, under certain circumstances, the option not to require a review of MCO or PHP compliance with certain structural and operational standards specified in proposed § 438.358(a)(2) if the MCO or PHP is a certified M+C organization with a current Medicare contract, and has been evaluated and approved by us, our contractor, or certain approved accrediting organizations as a part of accreditation for compliance with these standards. The December 1, 1999 proposed rule also provided that a State agency under certain circumstances may similarly avoid duplicate reviews of all mandatory activities (listed in paragraphs (a)(1) and (a)(2) of proposed § 438.358) for any MCO or PHP that serves only individuals who are eligible for both Medicare and Medicaid. Under the December 1, 1999 proposed rule, if the State agency exercises this option, each MCO and PHP must make available to the State agency all reports, findings, and other results of the Medicare quality review or the accreditation survey that is to substitute for the Medicaid review.

Comment: Several commenters supported provisions designed to avoid duplication in the EQR process.

Response: We retain the nonduplication provisions in the final rule while providing clarifying language on their applicability, as discussed in responses to comments below, in order to better explain our intent.

Comment: Several commenters asked that the provisions in this section not be restricted to Medicaid MCOs that have M+C contracts. The commenters believe that the BBA does not restrict the nonduplication provision to these organizations.

Response: We agree with the commenters that the BBA does not require that an M+C contract be in place in order for the nonduplication provisions to apply. In response to these comments, we have changed the final rule to allow States, under certain circumstances, to elect not to review structural and operational standards of an MCO or PIHP that has been accredited by a national accrediting organization approved by CMS under the procedures in 42 CFR 422.158 as applying standards at least as stringent as Medicare, where the standards are comparable to those imposed by the State under § 438.204(g). The EQRO must review the reports, findings, and other results of the accreditation review to use in the EQR.

Comment: Several commenters recommended that we amend our regulations to permit accreditation programs that address only a portion of the § 438.358(a)(2) requirements. One commenter wanted us to retain the provision that allows an EQRO to use a review conducted by a private accrediting organization, or as part of an external review conducted under the Medicare program. Another commenter suggested that we revise § 438.360(b) to allow a State to exempt an MCO from a review of the mandatory activities, as opposed to exempting the MCO from the mandatory activities.

Response: We agree with the commenters that a State should be permitted to use only certain portions of a Medicare or accreditation review in place of a portion of a Medicaid review. As stated above, the final rule provides States with the option of using a Medicare or (if approved by CMS under § 422.158) private accreditation review to serve as the Medicaid compliance review of any or all of the standards required to meet provisions under § 438.204(g) as long as the MCO or PIHP meets the requirements of § 438.360(b) or (c). Because we received numerous comments on the applicability of this provision, we have revised the language in this section to more clearly explain our intent to apply it to MCOs and PIHPs that have been reviewed by an accrediting organization approved under § 422.158. We also clarified the regulations text to better identify the activities and standards to which this section applies, and what information needs to be provided to States and us to comply with this provision.

Comment: One commenter did not agree with provisions in § 438.360(b)(3) or (c)(3) requiring that a State receive a copy of all findings pertaining to the most recent accreditation review. The commenter contended that standard-specific information is adequate and that all review materials such as noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements are excessive and unnecessary. The commenter suggested that we require MCOs to provide the State with applicable reports, findings, and results. Many commenters agreed that we should require that States receive and review information from the Medicare review or accreditation review.

Response: We agree that requiring all reports, findings, and other results of the Medicare review or accreditation review could be excessive. We have revised the language § 438.360(b)(3) and (c)(3) to reflect that the reports, findings, and results provided can be limited to those applicable to the standards for which the Medicare or accreditation review or quality activities will substitute for the Medicaid review activities.

Comment: One commenter asked us to clarify whether the nonduplication provision exempts the MCO from a review for compliance with standards, such as enrollee rights, maintaining a grievance system, or using practice guidelines. One commenter recommended that we allow deeming of credentialing and recredentialing requirements if the MCO is NCQA certified.

Response: We provide that the State may permit the findings from other allowable reviews to substitute for a duplicate review of the structure and operations of the MCO or PIHP. Under this provision, an MCO or PIHP is not exempted from a review of standards under § 438.204(g). Rather, States are permitted the option of using Medicare reviews or accreditation findings, including a review of credentialing and recredentialing procedures, instead of conducting a separate (and potentially duplicative) review, as long as the provisions under § 438.360 are met. This would apply to information on compliance with standards such as the requirements set forth in proposed § 438.358(a)(2)(i) through (a)(2)(xiii) cited by the commenter.

Comment: Many commenters agreed that external reviews need to validate performance measures specific to the Medicaid population in the case of Medicaid contracts. In contrast, one commenter recommended that an MCO fully accredited by a private accrediting organization should also be exempt from calculating performance measures (for example, HEDIS). The commenter believed that this would eliminate the need for new-capacity building or criteria to ensure consistency.

Response: We do not agree that an accredited MCO or PIHP should be exempt from a validation of performance measures calculated under § 438.358(a)(1) unless it provides services to dual eligibles only. As stated in our December 1, 1999 proposed rule, we believe the types of data collected, measures calculated, and studies conducted, on the Medicare population would differ from those for the Medicaid population unless the MCO or PIHP served only dually eligible Medicare and Medicaid beneficiaries. We believe this argument is also valid when applied to the commercial population. We, therefore, retain the language as written in the December 1, 1999 proposed rule. We note that if the accrediting organization, acting as the EQRO of the State, validates the performance measures required of the MCO or PIHP by the State, the State can obtain the 75 percent match under section 1903(a)(3)(C)(ii) of the Act for having the accrediting organization conduct that activity.

Comment: One commenter recommended that we revise the regulation to give State agencies discretion to determine what EQR activities are duplicative.

Response: We do not agree that States should have discretion to determine what EQR activities are duplicative. Except in the case of an MCO or PIHP that provides services to dual eligibles only, we limit the nonduplication provisions to the structure and operational standards reviewed under § 438.358(b)(3).

Comment: Several commenters noted that accrediting organizations differ in how they characterize the status conferred when MCOs meet their accreditation standards. For example, these commenters pointed out that not all accrediting organizations use the term ''full accreditation.'' One commenter recommended that we clarify proposed § 438.360(b)(2)(ii) to avoid confusion regarding what accreditation level must be attained to meet the requirements of the paragraph. Another commenter asked us to clarify ''fully accredited'' and recommended that we negotiate with accreditors seeking to be recognized under this section to determine what type of accreditation would meet the intent of this section.

Response: We understand that accrediting organizations use different terms to describe the extent to which MCOs or PIHPs meet their standards. However, in this provision of the regulation, we are not requiring that the MCO or PIHP achieve a certain level of accreditation. Rather, we are allowing States to use information gathered in the private accreditation process that is shared with the State to assess compliance. To make this more clear, in response to this comment, we have removed the term ''fully accredited'' from the regulations text. We also have revised the language of this section in order to make our intent more clear. We now specify that accrediting organizations that have been approved by us for M+C deeming under § 422.158 meet the requirements of this provision.

Comment: Several commenters did not agree with permitting States to avoid mandatory activities by relying upon information gathered from a Medicare or private accreditation review in order to assess MCO compliance with structural and operational standards. Some of these commenters specifically strongly opposed the exemption from mandatory activities when an MCO has a Medicare contract. They believed that activities such as review for the availability of services, establishment of provider networks, enrollee information, confidentially, and use of practice guidelines all have Medicaid and pediatric components that would not be examined under a Medicare review. If an exemption is allowed, the commenters suggested that additional activities be required to ensure compliance in problem-prone or sensitive areas that reviews by Medicare or private accrediting organizations may not adequately address. One of the commenters recommended that if an MCO is being considered for the exemption, that there must be substantial overlap between the Medicare and Medicaid products in (1) geographic service area, (2) network composition and management, (3) quality management structures and processes, and (4) levels of accreditation. Many commenters suggested that unless our quality review or accreditation has established the quality of the Medicaid provider network and administrative structures, these activities should not be exempted under nonduplication.

Response: The Congress clearly intended that we provide States the option to avoid duplicating review activities conducted for Medicare or by accrediting organizations. We limit the applicability of this provision to the mandatory activity designed to help States assess structural and operational standards for all MCOs and PIHPs other than those serving only dual eligibles. For the latter, under § 438.360, we also permit States to use this option with respect to the validation of performance measures or the validation of performance improvement projects. We believe proposed § 438.360 generally places sufficient parameters on States that choose to exercise this option.

We retain the provision that permits States to use this option to assess compliance with standards. We note that § 438.207 of the Medicaid managed care final rule requires that MCOs and PIHPs submit documentation to the State of compliance with requirements in the Medicaid managed care final rule that requires MCOs and PIHPs to maintain a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the enrollees in the MCO or PIHP. In addition, § 438.207 requires that any time there has been a significant change in MCO or PIHP operations that would affect adequate capacity, additional documentation must be submitted. We believe this information adequately complements any review of availability of services that would be conducted by Medicare or an accrediting organization that provides information for the EQR.

We are concerned, however, that the wording of proposed § 438.360 has caused some confusion about the intent of this provision. Specifically, our words ''A State may exempt an MCO from mandatory activities * * *'' may be interpreted by some as exempting an MCO or PIHP from oversight, rather than an exemption from State Medicaid reviews that duplicate Medicare and private accreditation reviews. To clarify this, we have removed the word ''exempt'' from this provision in the final rule (noting also that the Congress did not use this word in the corresponding statutory provision) and replaced it with language reflecting the fact that these provisions do not exempt MCOs from review for compliance with structural and operational standards, but instead permit States to use information generated through Medicare or private accreditation review to assess compliance with these standards, in lieu of engaging in their own otherwise ''mandatory'' review activity.

In addition, in response to the commenters' concerns about permitting States to substitute Medicare or private accreditation review for direct State review, we are adding a new paragraph (4) to § 438.360(b) and (c) requiring that States identify in their qualities strategies those standards and activities they plan to monitor through the use of Medicare or private accreditation review data, and explain why direct State review would ''be duplicative.'' This will help ensure that this approach is only taken when State review would truly be needlessly duplicative of review already performed.

Comment: One commenter was concerned that proposed § 438.360 appeared to allow the nonduplication exemptions to last indefinitely, and believed that it was not unusual for plan performance to vary significantly from year to year due to organizational changes. The commenter recommended that States be required to develop mechanisms to periodically re-evaluate MCO compliance with standards during the course of a 3-year period, and to re-institute a direct Medicaid agency review if accreditation, Medicare, or State oversight indicate potential quality problems.

One of the commenters cited recent OIG studies that identified significant issues with accrediting bodies, and did not think that States should relinquish their direct MCO oversight responsibilities to the accreditation industry.

Response: Neither the statutory nor conference committee language discussed any time limit on a State using Medicare or accreditation review data in its assessment of an MCO or PIHP in lieu of a direct Medicaid review. We believe it appropriate to allow States to make the determination as to whether this remains appropriate. We note that the new paragraph (4) that we have added to § 438.360(b) and (c) requires that States explain and justify their use of this approach, and believe that it is appropriate to permit the approach to be used for so long as this justification remains valid. Therefore, we do not specify a time limit in the final rule.

With respect to the commenter's recommendation for periodic re-evaluation every 3 years, § 438.360 requires that information obtained from a Medicare review or a review by an accrediting organization be provided to the State, which must then provide the information to the EQRO for use in the EQR. Because this information must be obtained from a review of compliance with standards conducted within the past 3 years, this requirement should address the changes in plan performance that the commenter is concerned about. Moreover, the Medicaid managed care final rule requires that States have a quality strategy that has procedures for assessing the quality and appropriateness of care provided to

Medicaid beneficiaries, and that States must regularly monitor and evaluate MCO and PIHP compliance with operational standards.

As noted in earlier responses, we believe the Congress clearly intended States to have the option of avoiding duplicate reviews of MCOs that have been accredited by a national accrediting organization, and we accordingly allow for this in the final rule.

Comment: One commenter recommended that we clarify that States may only eliminate elements of the EQR process, whether mandatory or optional, if components of the M+C evaluation process or private accreditation review are the same as or similar to those of the Medicaid review process. Several commenters felt that this provision should address two concepts: whether the standard or requirement is duplicative, and whether the methodology of the review is duplicative. One commenter asked that we clarify what we mean when we say, under § 438.360(b)(2), that the ''* * * methodologies must be * * * established by the State, not CMS.'' The commenter noted that it is the State, not CMS, that establishes the standards for the mandatory activity under § 438.358(a)(2) and therefore it is not clear what benchmark we intend to use to determine comparability.

Response: This section of the regulation applies only to mandatory activities as specified in § 438.358(b). Because the optional activities are not required, we do not address optional activities in the nonduplication provisions. As stated earlier, we have clarified the regulations text to better explain that Medicare or accreditation standards must be comparable to those established by the State. We have removed the reference to standards and review procedures needing to be as stringent as those established by CMS because we agree with the commenter, that it is the State, not CMS, that will establish standards to comply with § 438.204 of the Medicaid managed care final rule. As for review methodology, the statute required that we establish protocols to be used in EQR. The protocols we developed include generic activities and steps to be followed to ensure that the EQR activities are conducted in a reliable and valid manner.

Comment: One commenter asked that, because implementation of proposed § 438.360(b)(2)(ii) would depend upon our approval and recognition of private accrediting organizations under § 422.158 as having standards and review procedures as stringent as those established by Medicare, we move forward to make these later determinations so this provision can be implemented in a timely fashion when these regulations become final.

Response: We have already received and approved applications for M+C deeming from several accrediting organizations: (1) NCQA, (2) JCAHO, and (3) the Accreditation Association for Ambulatory Health Care (AAAHC).

Comment: One commenter was confused about the distinction between proposed § 438.360 and proposed § 438.362, and felt they were redundant. The commenter also objected to our provisions applying to dual eligibles, specifically the State's option of permitting information obtained from performance improvement projects and performance measures specific to dual eligibles to substitute for Medicaid specific information.

Response: We do not agree that § 438.360 and § 438.362, which permit States to exempt an MCO or PIHP from EQR in its entirety, are redundant. However, we agree that proposed § 438.360 was potentially confusing in its use of the word ''exempt.'' We have revised the language in § 438.360 to clarify that § 438.360 allows States to use the findings of Medicare or accreditation reviews in place of a Medicaid review in order to avoid duplication, but does not exempt MCOs or PIHPs from EQR, as does § 438.362 where it applies. We think that there is a clear distinction between § 438.360 under which analysis and evaluation of information must still be conducted, and § 438.362 under which the MCO or PIHP is exempted from the EQR function. We disagree with the commenter concerning the appropriateness of the dual eligible provision. In the case of dual eligibles, Medicare review necessarily is targeted to the population involved. We therefore believe that Medicaid review could be particularly duplicative in this case.

Comment: One commenter requested that if accreditation is to be used as the basis for exemption, regulations require that the MCO be specifically accredited with respect its Medicaid line of business, and that information from this Medicaid enrollee review be provided to the State.

Response: We do not agree that we should limit the applicability of the nonduplication provisions in § 438.360 to MCOs or PIHPs accredited specifically for their Medicaid product. Most accrediting organizations do not conduct separate reviews for an MCO's or PIHP's Medicaid product. With respect to the commenter's second point, we do require that the findings of the accreditation be provided to the State and then, in turn, to the EQRO to be used as part of the EQR.

Comment: One commenter urged that we allow for the use of review findings of related ''focus studies'' of groups that Medicaid serves (for example, the elderly or disabled) which are conducted by other types of certified Medicare organizations.

Response: As long as a focused study is conducted using a methodology consistent with our protocols, and the study population is composed of Medicaid beneficiaries, a State can have its EQRO use the review findings. In addition, if the organization that conducts the focused study is the State's EQRO, the State can obtain the 75 percent enhanced match for its review of these findings.

Comment: One commenter believed that the activities under proposed § 438.358(a)(2) are not the same regardless of the populations served, and specifically that there is a difference when serving individuals with disabilities. To address this concern, the commenter felt that the EQRO must be knowledgeable and sensitive to people with disabilities in order to effectively assess an MCO's compliance with standards.

Response: As specified in § 438.354, an EQRO must meet certain competency requirements, including having staff with knowledge of Medicaid beneficiaries. In addition, our Medicaid managed care final rule requires, under the State's quality strategy, that the State have procedures in place for assessing the quality and appropriateness of care and services furnished to enrollees with special health care needs. This includes individuals with disabilities.

Comment: One commenter recommended that audits conducted by the State licensing organization be coordinated with the EQRO, and that the audit of components conducted by the State licensing organization be ''deemed'' to have been performed by the contracted EQRO.

Response: States can use their State licensing organization to assess MCO or PIHP compliance with State standards, or perform any of the mandatory or optional EQR-related activities identified in § 438.358. If a State wants to use this information for the EQR, the review must, at a minimum, use our protocols or protocols that are consistent with ours. Thus, there would be no reason to ''deem'' these reviews to have been performed by the EQRO, other than to claim the 75 percent match that would apply if the EQRO performed these functions. As noted

above, however, if a State uses entities other than EQROs to perform activities, the 75 percent match rate under section 1903(a)(3)(C)(ii) of the Act would not be available. We hope and anticipate that States will coordinate the EQR and EQR-related activities with other State quality activities currently in place.

Comment: Many commenters believed that direct Medicaid agency external reviews should always be performed with respect to grievance systems because these commenters believe that the Medicaid fair hearings process is unique.

Response: The EQRO is not responsible for reviewing the State's fair hearing process. It must review information about the MCO or PIHP internal grievance system. In order for a State to use a Medicare or accreditation compliance determination to substitute for a Medicaid review of the MCO's or PIHP's grievance system, the State will need to address in its quality strategy the basis for considering the Medicare or accrediting organization's standard comparable to the State's grievance processes standard that needs to comply with the provisions of subpart F of the Medicaid managed care final rule.

Comment: One commenter expressed concern that we excluded Medicare beneficiaries who are eligible for Medicaid as a result of spenddown requirements from the definition of dually eligible persons.

Response: We have not excluded from the definition of dually eligible those Medicare beneficiaries who are eligible for Medicaid as a result of spenddown requirements. We consider any person who is receiving both Medicare and Medicaid benefits as a ''dually eligible'' person.

Comment: One commenter believed that the meaning of MCO in proposed § 438.360, and § 438.362 was not clear. The commenter noted that corporate entities may be wholly owned subsidiaries of other corporate entities, and may hold multiple licenses. The commenter also noted that in some cases a plan may have a large Medicaid product and a very small Medicare product, calling into question the assumption that adequate management of the Medicare enrollees is an appropriate proxy for their Medicaid enrollees. The commenter recommended a more complete definition of MCO, as it relates to the MCO's Medicare and Medicaid product lines being incorporated into the rule.

Response: The definition of MCO as used in this regulation is defined in § 438.2 of the Medicaid managed care final rule. According to this definition, an MCO is the entity that holds the Medicaid comprehensive risk contract. We believe that this definition addresses the commenter's concern, as the Medicare review provisions will only apply if the same entity that holds the Medicaid contract holds the Medicare contract.

Comment: One commenter recommended that we make clear that a State may undertake optional EQR activities, even if it has exempted an MCO from a portion of or all of the mandatory activities.

Response: A State may conduct the optional EQR activities when it uses Medicare or accreditation review findings for the mandatory activities. As long as the State uses the protocols developed by us or protocols consistent with ours, the information derived from the optional activities can be used in the EQR.

Comment: One commenter believed that when an MCO is accredited by a private accrediting body, the States should be strongly encouraged not to duplicate the review performed by the private accrediting body.

Response: The final rule provides States the option to use the findings of an accrediting body instead of conducting its own review of MCO or PIHP compliance with certain standards, if the MCO or PIHP has been accredited by a national accrediting organization recognized by us. We believe that States should have the discretion to make this decision, and individuals who believe that this option should be adopted should encourage States to do so.

I. Exemption From External Quality Review (§ 438.362)

Proposed § 438.362 provided an option for a State agency to exempt an MCO or PHP from the EQR requirements in section 1932(c)(2)(A) of the Act if: (1) The MCO or PHP has a current Medicare contract under part C of title XVIII or under section 1876 of the Act; and (2) for at least 2 years, the MCO or PHP has satisfied EQR requirements under section 1932(c)(2)(A) of the Act with respect to its Medicaid contract. In addition, we proposed that the Medicaid and Medicare contracts be required to cover all or part of the same geographic area. We also proposed that the State agency require each exempted MCO and PHP to annually provide the State with copies of all Medicare reviews performed by us, by our agent or any private accrediting organization, with respect to the quality, timeliness, and access to its services.

Comment: Many commenters opposed this exemption of certain MCOs from EQR. One of the commenters felt that this provision completely abrogates the responsibility of the States and CMS to monitor the quality of Medicaid managed care systems for children. One commenter agreed with this provision, as long as it was an option for States.

Response: In the BBA, the Congress expressly provided States with the option of exempting from EQR those MCOs that provide Medicare services and also have had experience serving the Medicaid population. This provision, however, does not exempt States from monitoring MCOs and PIHPs for compliance with the mandatory activities listed in § 438.358. These activities, required of MCOs and PIHPs under our Medicaid managed care final rule, are essential to ensure the quality of services provided to Medicaid beneficiaries by MCOs and PIHPs. For example, the BBA requires that States have a quality strategy in place when contracting with MCOs and PIHPs. States will still need to ensure MCO and PIHP compliance with the BBA provisions and our regional offices will continue to monitor States for compliance regardless of whether or not an EQR is conducted.

Comment: One commenter asked how this provision would impact a Medicaid plan that gave up its M+C product. Specifically, the commenter asked if there would be an immediate requirement for an EQRO review.

Response: Under § 438.362(a)(1), the MCO and PIHP must have a current Medicare contract. Therefore, as EQR is an annual requirement, the year following the termination of the M+C plan, the State is required to contract with an EQRO to, at a minimum, review and analyze information from the validation of performance improvement projects conducted by the MCO or PIHP and performance measures calculated by the MCO or PIHP that year. The State will also need to ensure MCO or PIHP compliance with structural and operational standards. If the MCO or PIHP had been reviewed by Medicare or an accrediting organization within the previous 3 years, that information could be used in the EQR. If this were the year that the MCO or PIHP was to be reviewed for structural and operation standards, the State or its contractor, or the EQRO would have to conduct a review.

Comment: Several commenters asked us to clarify who we considered appropriate to determine whether an MCO or PIHP performed acceptably in previously conducted EQRs, as this was not a requirement under the section 1902(a)(30)(C) of the Act EQR requirements. Some of the commenters

stated that it would not be appropriate for the State to make the determination, as the independent nature of the EQR might be compromised. Many commenters asked us to clarify what we consider to be acceptable performance and recommended that an MCO or PHP be required to perform acceptably on quality, timeliness, and access in order for a State to allow for the exemption.

Response: Whether an MCO or PIHP has performed acceptably is determined by the State based on the results of the EQR, which must include a detailed assessment of each MCO's and PIHP's strengths and weaknesses with respect to quality, timeliness, and access to health care services provided to Medicaid beneficiaries. If a State elects to exempt an MCO or PIHP from an EQR it must, as specified in § 438.362(a)(3), ensure that an MCO or PIHP not only have had a Medicaid contract for 2 years but that the MCO or PIHP has also been subject to an EQR as specified in this rule. This effectively means that no MCO or PIHP could be exempted under § 438.362 until EQR under this final rule is in effect for at least 2 years. As long as the provisions under this section are met, the State will determine the length of time for which it will exempt an MCO or PIHP from EQR. The State will be able to use information obtained from the Medicare or accreditation reviews, as the submission of Medicare review findings is required under § 438.362(b).

Comment: One commenter was concerned that similar geographic coverage areas do not necessarily ensure similar administration, networks, benefits, and quality improvement projects for the different beneficiaries who are served by the Medicare and Medicaid programs. Another commenter agreed with the requirement that the two contracts cover the same geographic area, but was concerned that practice patterns tend to vary geographically for given clinical topics and specific types of treatment. The commenter suggested we change the geographic requirement to require similar or identical service areas instead of overlapping areas. Two commenters supported the requirement that the two contracts cover all or part of the same geographic area, but suggested that we include additional requirements that the two contracts must (1) include the same provider networks and (2) offer the same or similar benefit and services to consumers. The commenters believe this is important because M+C plans serve markedly different populations, provide different benefit packages, and often offer different provider networks than Medicaid plans. One commenter asked us to clarify whether the Medicaid and Medicare services areas have to be identical for MCOs and PHPs to qualify for exemption.

Response: Under § 438.362(a)(2), we require that the Medicare and Medicaid contracts cover all or part of the same geographic area in order for a State to exempt the MCO or PIHP from EQR. We required an overlap of service areas in this provision because we believe this will increase the likelihood that the findings from the Medicare review will serve as a proxy indicator of the care delivered to the MCO's or PIHP's Medicaid beneficiaries. We have made some clarifying language changes to the regulations text in the final rule to more clearly state our intent that the contracts must cover all or part of the same geographic area within the State that is allowing the MCO or PIHP exemption from EQR. However, we think that requiring identical service areas or the same or similar benefit packages is too restrictive, and may effectively exclude the use of an exemption intended by the Congress.

Comment: Several commenters asked that we not restrict the exemption provision to M+C organizations, but also allow it to apply to MCOs and PHPs that have undergone or achieved ''excellent'' status by a private accreditation review.

Response: In the BBA, the Congress applied the total exemption in section 1932(c)(2)(C) of the Act only to M+C organizations. Consequently, we have not applied this provision to commercial MCOs and PIHPs. However, we address nonduplication provisions related to EQR activities as they apply to private accreditation under § 438.360.

Comment: Several commenters concurred with the requirement that an MCO or PHP must demonstrate acceptable performance determined by the EQR for the 2-year period before exemption. One of these commenters, however, was concerned that the regulation appears to allow exempt status to last indefinitely, and noted that it is not unusual for plan performance to vary significantly from year to year due to organizational changes. Several commenters recommended that States be required to develop mechanisms to periodically re-evaluate an MCO's exempt status, and to re-institute EQR if accreditation, Medicare, or State oversight indicate potential quality problems. One commenter opposed our proposal to require that the MCO have complied with EQR requirements for 2 prior years. This commenter believed that this interpretation was unduly restrictive, and inappropriately limited the discretion given to State agencies to exempt MCOs based on the State agencies' experience with the MCOs or PHPs.

Response: We believe that the language in this rule properly reflects congressional intent to allow States the option to exempt a Medicare MCO from EQR. Once an entity is exempted, and continues to meet the criteria for exemption, we believe that the Congress intended that the Medicare quality review requirements serve as a proxy for the Medicaid EQR requirements. Because the State will have access under § 438.362(b) to data from these reviews, any problems that develop should be recognized through this process. We thus do not believe it would be appropriate to require States affirmatively to re-evaluate an MCO's or PIHP's EQR-exempt status.

With respect to our requirement that 2 years of success in Medicaid EQR be required, as noted in the preamble to the proposed rule, we considered several interpretations of the statutory provision that requires at least 2 years of Medicaid contracting in order for this exemption to apply. We concluded that the Congress' intent in requiring 2 years of Medicaid contracting experience was to ensure that the MCO had sufficient quality measures in place to meet Medicaid EQR standards before it could be exempted from Medicaid review. Since these EQR standards are new, this necessarily would require that an MCO have a Medicaid contract for 2 years under these EQR requirements before the exemption in § 438.362 would apply. This ensures that all MCOs and PIHPs have been subject to Medicaid EQR at some point, and have been found to be compliant with Medicaid standards in this review.

We emphasize again, however, that the EQR requirements, from which MCOs and PIHPs can be exempted under § 438.362 are only one part of the Quality Strategy provided for in the BBA. Other BBA provisions require States contracting with MCOs to ensure the quality and appropriateness of care and services furnished to Medicaid beneficiaries. We believe that if States find MCOs or PIHPs not to be providing appropriate quality care, they would exercise their option to require an EQR.

Comment: Many commenters agreed that MCOs should be required to submit copies of reviews performed by Medicare or an accrediting organization. One commenter did see the benefit in receiving Medicare review reports. One of the commenters cautioned that accreditation reviews are generally performed less frequently than annually.

Response: We only require that information from the Medicare or

accreditation review be provided annually. We are not requiring that Medicare or accreditation reviews be conducted annually. If no new information is obtained in a specific year, it is not necessary for the MCO or PIHP to provide the State information provided the previous year. If a State chooses to exempt the MCO or PIHP, this does not relieve the State from ensuring that access to timely and quality services is being provided. Findings from a Medicare or accreditation review will provide the State a useful source of information to determine access to quality services for Medicaid beneficiaries. To better explain the types of information we are requiring be provided if a State chooses this option, and to address situations in which an entity is accredited by a private accrediting body approved by CMS under § 422.158, we have added clarifying language that makes a distinction between when a Medicare review is conducted by us or our contractor and when an accreditation review based on deemed compliance by such an approved entity. The findings of an accreditation review of an MCO or PIHP must be from a review of the Medicare line of business as this provision only applies to an M+C organization.

Comment: Many commenters recommended that MCOs that have established distinct provider networks for Medicaid and Medicare beneficiaries not be exempt from EQRs.

Response: As explained in an earlier response, we attempted to address differences inherent in Medicare and Medicaid contracts by requiring the contracts to have some geographic overlap. We do not believe, however, it is necessary or appropriate to require that Medicare and Medicaid beneficiaries of the MCO or PIHP use the same providers. We believe that an MCO or PIHP that demonstrates satisfactory compliance in M+C external review has demonstrated that it has appropriate quality safeguards in place, and that these would extend to all providers, whether seen by Medicare, Medicaid, or commercial enrollees.

We note that in providing for this exemption in section 1932(c)(2)(C) of the Act, the Congress did not require that Medicare and Medicaid enrollees use the same providers. It did require, however, that the entity have 2 years of Medicaid contracting experience. Under our interpretation of this requirement, discussed in a previous comment response, an MCO or PIHP would be required to demonstrate satisfactory results from 2 years of Medicaid EQR under part 438 before it would be eligible for the exemption under § 438.362. Thus, even if different providers are used by Medicaid enrollees than Medicare enrollees, the MCO or PIHP would have demonstrated for 2 years that the Medicaid providers performed satisfactorily in EQR before being exempted from this review. Having already demonstrated that its Medicaid providers met quality standards, the fact that it continues to satisfy quality standards in future years under Medicare external review is an indication that the entity is continuing its level of commitment to quality.

Comment: Many commenters recommended that the regulations specify that in the case of mergers and acquisitions, MCOs be treated as new contractors in the Medicaid program, and be subject to an EQR.

Response: We do not agree with the commenter that the regulations should specify that all MCOs and PIHPs that have been acquired or merged with another MCO or PIHP be treated as new contractors. There are a variety of scenarios that occur when a merger or acquisition occurs as indicated by the complex rules that govern how private accrediting organizations address these situations. In addition, States have their own laws and regulations governing mergers and acquisitions. We, therefore, believe the States are in the best position to determine quality improvement requirements for newly formed entities and this regulation provides States the option to allow for the exemption as long as all the provisions in this section are met.

Comment: One commenter asked that we revise § 438.362(b)(1) to specify that the State agency must require each exempted MCO to provide it annually with copies of Medicaid reviews performed by State agents or any private accrediting organization with respect to the quality, timeliness, and access to services instead of Medicare review findings.

Response: We are not revising § 438.362(b)(1) to require Medicaid review findings be submitted to the State because if a State or its agent conducted a review, there would be no need to require the MCO or PIHP to submit the review findings, as the State would already have this information. There is a need, however, for the MCO or PHP to submit Medicare review findings if a State chooses to exempt an MCO or PIHP from EQR, which is why this requirement is included in § 438.362(b). The exemption provision does not relieve a State from the responsibility for ensuring the adequacy of care provided by an MCO or PIHP, and the data from Medicare quality reviews are a source of information that will be necessary for States to use to determine the appropriateness of exempting an MCO or PIHP from an EQR the following year.

Comment: One commenter recommended allowing States the flexibility to decide if their Medicaid services can properly be evaluated by a Medicare review.

Response: States have the flexibility to determine if Medicaid services can be appropriately evaluated by a Medicare review. This provision provides States with the option to exempt an MCO or PIHP from EQR. It does not require the exemption.

J. External Quality Review Results (§ 438.364)

In § 438.364, we proposed a requirement that the product of EQR be a detailed technical report, containing (1) a detailed assessment of each MCO's and PHP's strengths and weaknesses with respect to quality of the health care services furnished to Medicaid enrollees, (2) recommendations for improving the quality of the services furnished by each MCO and PHP, (3) comparative information about all MCOs and PHPs as determined appropriate by the State agency, and (4) an assessment of the degree to which each MCO and PHP addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR. Proposed § 438.364 also specified that the State must provide the results of the EQR to members of the general public upon request, and that the information released may not disclose the identity of any patient.

Comment: One commenter suggested that, because of the differing nature of adult and child health care needs, all data produced during the course of an EQR should be available by age groups so that parents may choose an MCO on the basis of the provision of quality pediatric care.

Response: This rule requires information from a variety of activities to be provided to an EQRO and included in the analysis and evaluation of the care provided by MCOs and PIHPs. Not all of the EQR activities provide detailed information that can be broken out by age groups or other categories. For example, a review for compliance with structural and operational standards would not yield beneficiary specific information. However, encounter data could potentially provide that information. In addition, the populations served by MCOs and PIHPs are likely to vary along multiple dimensions, including age,

income, diagnosis, and ethnic group. Because of the variability in the populations served by particular MCOs and PIHPs, we have provided States flexibility to determine the content of the results made available and the manner in which it is presented. To the extent that this information identifies quality issues pertaining to a specific population, the State may include that information in the results it makes available. However, we are not in the final rule requiring that EQR results be available by age groups, as this may not always be possible or appropriate for a given MCO or PIHP or for given data.

Comment: One commenter contended that not all quality improvement studies monitor quality, timeliness, and access. The commenter accordingly suggested that neither the State nor the EQRO should be required to summarize the strengths and weaknesses of the MCO or PIHP for each of these elements. The commenter also believed that if multiple studies are conducted, project time lines are not likely to coincide. In addition, the commenter recommended that proposed § 438.364(a)(5) be revised to require ''An assessment of the degree to which each MCO has addressed effectively the recommendations for quality improvement as made by the EQRO during the previous measurement of the measure or of a similar measure, as appropriate to the study performed.''

Response: The commenter suggesting that the State or EQR should not be required to summarize strengths and weaknesses of an MCO or PIHP for ''each of the elements'' of quality, timeliness, and access implies that the results of the EQR process need not address all three of these areas. Because section 1932(c)(2)(A) of the Act requires that an annual EQR include all three of these elements, it is essential that strengths and weakness identified by the EQR process with regard to each are described in the results. Because there appears to be confusion on this point, we have revised § 438.364(a)(1) to specifically reference ''timeliness and access.''

The commenter's suggestion that § 438.364(a)(5) be revised to permit the use of a ''previous measurement of a measure,'' as opposed to the previous year's EQR recommendations (as the baseline against which improvements in MCO or PIHP performance are assessed) is inconsistent with the clear direction of section 1932(c)(2) of the Act that EQR be an annual review. Further, the Medicaid managed care final rule requires performance measurement and improvement projects be underway on an annual basis. Consequently, we retain but modify the language of the proposed rule requiring the EQR to contain as assessment, as opposed to a ''detailed'' assessment of the degree to which each MCO and PIHP has addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR.

Comment: One commenter believed that the reference to ''strengths and weaknesses'' in proposed § 438.364(a)(2) implies a subjectivity that the commenter found inappropriate in carrying out the EQRO's responsibilities. The commenter recommended that the EQRO be required to report objectively on the performance of each MCO based on the measures selected. This commenter also questioned whether having an EQRO make recommendations for improving care and assessing the degree to which an MCO has met the previous year's recommendations are appropriate elements of the reports, because this is currently—and appropriately in the commenter's view—the province of the State (that is, identifying deficiencies in contract performance and holding MCOs accountable for correcting these deficiencies). The commenter requested that we exclude from the EQR reports, an EQRO's recommendations for improving care and assessing the degree to which the previous year's recommendations were met. If we retain these provisions, the commenter asked that § 438.364(a)(3) be revised to (1) allow the MCO the opportunity to submit a corrective action plan, which, if accepted would be adopted by the EQRO as its recommendation or (2) at a minimum, have the opportunity to comment on the EQRO's proposed recommendations. The commenter also suggested that § 438.364(a)(5) be revised so that the recommendations made by the EQRO are reviewed and approved by the State before finalizing the recommendations.

Response: We do not agree with the commenter that the report of EQR results should not address MCO and PIHP strengths and weaknesses. While we agree that the EQRO should consider the information produced by various EQR-related activities in an objective manner, the results of the analysis and evaluation of information will likely identify differences in the performance of MCOs and PIHPs with respect to issues under study. We believe that it is reasonable to expect the EQRO to be able to identify MCOs and PIHPs that had higher or lower scores on the State's standardized performance measures, and MCOs and PIHPs that had stronger evidence of compliance with certain standards. It is also reasonable for interested parties to expect this information to be publicly available. We note that this is common practice in the private sector where private accrediting organizations release comparative information on health plans.

We agree with the commenter that the State is the entity responsible for holding MCOs and PIHPs accountable for contract performance. The EQR is a source of information States can use to determine the adequacy of MCO and PIHP contractual performance regarding quality, timeliness, and access to services. The State may choose to require MCOs and PIHPs to submit corrective action plans based on the EQR results. In addition, as the State is the entity that holds the contract with the EQRO, the State may specify that it have the opportunity to review, comment, or approve the recommendations. The EQR results will be provided to us upon request, and will most often be requested and used by our regional office staff when conducting managed care program monitoring reviews. As a result, we retain the language included in the proposed rule.

Comment: One commenter concurred with proposed § 438.364, and specifically supported the requirement that EQR results (including assessments of MCO strengths and weaknesses and recommendations for improvement) be documented in sufficient detail and made publicly available. The commenter felt this was vital in order to allow interested parties to evaluate the conclusions of the EQR. Another commenter concurred with proposed § 438.364, and noted that the report required therein could be made available on the internet, to all interested parties, thus reducing the burden of report distribution.

Response: We agree with the commenters. Because the proposed language at § 438.364(b) could be interpreted to require the release of information in hard copy format only, in response to this comment we have modified the regulations text to indicate that the State must provide the information specified in paragraph (a) of this section, upon request, through print and electronic media, to interested parties.

Comment: One commenter noted that State staff currently perform the activities in paragraph (a)(2) of proposed § 438.364, and that requiring an EQRO to do this would increase the cost of the EQRO contract. The commenter also believed that the EQRO should not be making recommendations on improving the health care services furnished by each MCO, as specified under paragraphs (a)(3) and (a)(5) of proposed

§ 438.364. The commenter felt that the MCO should be responsible for designing interventions for improving its members' quality of care, and the EQR process should evaluate the effectiveness of these MCO interventions. Another commenter recommended these sections be deleted, contending that the Act does not require an external entity to perform any of the activities listed under paragraphs (a)(2) through (a)(5).

Response: As stated earlier, we agree that the State is ultimately responsible for rendering decisions about MCO and PIHP performance, and that EQR results represent one source of information States can use to determine MCO and PIHP performance. However, the Congress, in the BBA, stated that the EQRO is to perform a review of ''the quality outcomes and timeliness of, and access to the items and services for which the organization is responsible.'' The Congress further required that the results of the reviews be made available to multiple parties. We believe that a review requires the EQRO to make judgements regarding the MCOs' and PIHPs' performance in these areas and that the judgements can reasonably be expected to point to the MCOs' and PIHPs' strengths and weaknesses, recommendations about the quality, timeliness, and access to services provided by MCOs and PIHPs, and for how to make improvements. In order to enable the EQR process to be as effective and useful as possible, we retain these provisions in the final rule.

Comment: One commenter recommended that the regulation specify that the EQR results be made available in alternative formats for persons with sensory impairments, when requested.

Response: This comment appropriately suggests accommodations for persons with disabilities. At the end of § 438.364(b), in response to this comment we have added a sentence requiring States to make the EQR results available in alternative formats for persons with sensory impairments when requested.

Comment: Several commenters believed that while it may make sense to mandate disclosure of valid, reliable, and objective performance, and satisfaction measures, States should not be required to disclose the results of other health plan operations, such as contractual compliance, and quality improvement studies. In the view of these commenters, EQR activities should promote a frank assessment of performance in order to provide MCOs and PIHPs the knowledge necessary to perform better in the future. The commenters suggested that if the results of quality improvement studies were made public, MCOs would not treat the process as an unfettered opportunity to assess their own performance. Instead, the commenters believed they would tend to conduct studies in a way that is likely to generate favorable outcomes and, thereby, meaningful quality improvement efforts. One of these commenters also noted that if the primary audience for this information was Medicaid enrollees, we needed to consider whether such a detailed technical report would be relevant to our beneficiaries' needs.

Response: As we indicated in the preamble to the proposed rule, we proposed to require only that summary information made generally available is sufficient to enable interested parties to evaluate the conclusions of the EQR. The State is not expected to provide more detailed underlying data to beneficiaries or the general public. However, to clarify the level of detail to be provided in the EQR results, in response to this comment, we are revising § 438.364(a)(1)(iii) to require only that a description of data be provided in the technical report, as opposed to requiring that the actual data obtained be provided. Our intention was never to require that raw data be provided. In addition, as noted above, we are providing clarifying language in § 438.364(a)(1) to make clear that the technical report conclusions address timeliness and access to care as well as quality of care.

We note that section 1932(c)(2)(A)(iv) of the Act specifies that EQR results be made available to providers, enrollees, and potential enrollees. In the proposed rule, we broadened this requirement to specify that the results be made available to the general public. To ensure that adequate information is available for beneficiaries, as well as providers, beneficiary advocates, and other stakeholder, we believe that some detail in the report is warranted. In addition to making the EQR results available, States have the flexibility to repackage these results in order to address specific audiences more appropriately.

Comment: Many commenters agreed with our effort to ensure public access to EQR results. The commenters also recommended that the findings of private accreditation reviews be made available to the public when they substitute for all or part of the EQR. They stated that this is consistent with the President's Advisory Commission of Consumer Protection and Quality in the Health Care Industry recommendation that when a private accreditation is used, there must be full disclosure of the standards, survey protocols, and the detailed information from the surveys.

Response: Section 438.364 identifies the results of the EQR process that must be made available and to whom it must be made available. When an EQRO is using private accreditation or Medicare review results under the nonduplication option under § 438.360, the EQR results, in accordance with § 438.364(a)(1), must still include the information required under paragraphs (a)(1)(i) through (a)(1)(iv) of this section. We believe that when a State chooses to use the results of a Medicare or private accreditation review to replace a Medicaid review, that there must be information on the data obtained from the Medicare or accreditation review and conclusions drawn from the data consistent with § 438.364(a)(1)(iii) and (a)(1)(iv).

Comment: One commenter asked us to clarify whether the regulation envisions that the full technical report be available to the public, or whether only certain information about the technical report will be made available. The commenter recommended that we establish guidelines for preparation of a summary report that must be developed from the technical report. The commenter believes that a summary report will be more useful to the public and will avoid the potential for the release of proprietary information that might appear in the reports.

Response: As we stated in the preamble of the proposed rule, we are only requiring that States make available summary-level information that is ''sufficient to enable interested parties to evaluate the conclusions of the EQR.'' The State is not expected to provide more detailed underlying data or proprietary information to beneficiaries or the general public. As we noted earlier, to provide clarification on the level of detail to be provided in the EQR results, we are revising § 438.364 (a)(1)(iii) to require that a description of data be provided in the technical report as opposed to requiring that the data obtained be provided.

K. Federal Financial Participation (FFP) (§ 438.370)

Proposed § 438.370 provided that FFP would be available (1) at the 75 percent rate for EQR, the conduct of EQR activities, and the production of EQR results, by EQROs and their subcontractors, and (2) at the 50 percent rate for EQR-related activities performed by entities not qualifying as EQROS. The 50 percent rate applies even if the activities are of the same type as those that would be matched at the 75 percent rate if performed by an EQRO.

Comment: Several commenters asked us to clarify whether a State must contract with an EQRO in order to fulfill its EQR obligations under these regulations, and specifically whether it would fail to fulfill its obligation under the law if it contracts with an entity not qualified to be an EQRO.

Response: To fulfill its obligations under this regulation, a State must contract with an EQRO to conduct an analysis and evaluation of the aggregated information produced from, at a minimum, the mandatory EQR-related activities and produce the EQR results as required under § 438.364. In response to this comment, we have made clarifying changes to § 438.370 to better explain for what activities and functions States can obtain a 75 percent, or 50 percent match. That is, States can obtain the 75 percent enhanced match for EQR (the analysis and evaluation of information produced from EQR-related activities), EQR-related activities, and the production of EQR results as long as these functions and activities are conducted by an EQRO. States can obtain the 50 percent match for EQR-related activities conducted by entities not qualified as EQROs. However, States must contract with an EQRO that meets the requirements of § 438.354 to perform the EQR function of analyzing and evaluating the aggregate information from EQR-related activities. If a State did not so contract, it would be out of compliance with the requirement in section 1932(c)(2) of the Act for EQR.

Comment: One commenter asked whether the enhanced FFP is available for the optional activities a State may include in an EQR. Another commenter supported the enhanced FFP rates provided for in the Act.

Response: The enhanced FFP is available for the optional EQR activities as long as they are conducted by an EQRO that meets the requirements of § 438.354 using the appropriate CMS protocol or a consistent protocol.

Comment: One commenter requested clarification as to whether the upper payment limit (UPL) can be adjusted to take into account administrative expenses and if not, whether States will be able to request waivers of the UPL to reflect these additional expenses.

Response: The Medicaid managed care final regulation replaced the UPL requirements at § 447.361 with new rate setting rules (§ 438.6) by incorporating and expanding requirements for actuarial soundness. These new requirements recognize administrative costs and allow for States to adjust capitation rates to reflect MCO and PIHP administrative costs.

Comment: One commenter recommended that we revise § 438.370 to require States to appropriate a portion of the enhanced FFP to cover each MCO's administrative cost associated with meeting this EQR requirement.

Response: We believe that the statute does not permit States to use the enhanced funds to pay for MCO and PIHP administrative costs associated with EQR. The 75 percent enhanced match is only available for costs incurred by States for contracting with an EQRO. However, as noted above, with the elimination of the UPL, States now reflect administrative costs in capitation payments to MCOs and PIHPs.

Comment: One commenter asked us to clarify whether validation activities are reimbursable at the 75 percent enhanced FFP rate for EQR activities.

Response: The following validation activities are reimbursable at the 75 percent enhanced match as long as they are conducted by an EQRO that meets the requirements of § 438.354 and the EQRO uses protocols developed by us, or protocols consistent with our protocols: validation of performance measures, validation of performance improvement projects, validation of consumer or provider surveys, and validation of encounter data.

L. Miscellaneous Comments on the Preamble of the December 1, 1999 Proposed Rule

We noted in the preamble to the proposed rule that we followed two principles in its development: first, to provide flexibility to State agencies; and second, to reflect well-accepted advances in the methods of quality measurement and improvement.

The proposed rule also acknowledged that in a separate rule published in 1998, we had proposed to eliminate the requirements in § 434.53 that States have a system of periodic medical audits.

The proposed rule included a proposed effective date of 60 days following publication with provisions that must be implemented through contracts with EQROs to be effective with contracts entered into or revised on or after 60 days, but no longer than 12 months from the effective date. We received the following comments relating to the above issues.

Comment: Several commenters expressed support for the approach taken in the proposed rule in providing flexibility for States, and asked us to retain mechanisms States already have in place for EQR. Several commenters, however, found that the proposed rule did not afford States the flexibility and discretion afforded by the BBA. One commenter argued that States that demonstrate that their quality improvement processes meet or exceed the goals of these regulations should be permitted to continue with current arrangements. The commenter further contended that section 1932(c)(1)(B) of the Act, which requires that the Secretary's standards not preempt any State standards that are more stringent than those in the proposed rule, supports their position.

Response: Section 1932(c)(1)(B) of the Act refers to the quality assessment and improvement strategy that States are required to develop and implement. The components of this strategy were set forth in the Medicaid managed care final rule published on June 14, 2002. The EQR requirement is one component of this overall State strategy. We agree that the statute allows States to exceed the requirements of the quality assessment and improvement strategy as outlined in the Medicaid managed care final rule. However, the BBA also required the Secretary to undertake the activities set forth in this rule; that is, establish a method for identifying qualified entities to conduct EQR, develop protocols to be used for EQR, and otherwise implement the EQR provisions of the BBA. States will continue to have the flexibility to exceed the requirements included in this rule and conduct optional EQRO-related activities.

Comment: Several commenters asked us to explain how QISMC, the final Medicaid rules, and the EQR compose a cohesive vision and how States should integrate the proposed rule into other quality assessment and performance improvement activities. One of the commenters believed that the proposed rule appeared to set a standard for an overall evaluation rather than a specific external review study. Since QISMC sets overall standards, the commenter believed that a nonduplicative connection to QISMC was important. The second commenter asked us to clarify how the EQR regulations will fit in with current and pending State requirements.

Response: This final rule, as did the proposed rule, provides for an overall evaluation by an EQRO of the MCO's or PIHP's ability to provide timely and quality services to Medicaid beneficiaries as required by section 1932(c)(2) of the Act. The mandatory EQR activities are based on standards and activities that States must have in place under subpart D of the Medicaid managed care final rule.

Key elements of the QISMC document were incorporated into the Medicaid

managed care final rule, as appropriate. However, in other instances the QISMC standards, which we previously offered to States as guidelines and not requirements, were not appropriate as requirements in the regulations text. Further, the QISMC standards in a number of ways have become outdated. For example, the QISMC document does not sufficiently address individuals with special health care needs. Individuals looking for a cohesive vision of a quality improvement system for Medicaid managed care should look to three documents: (1) The Medicaid managed care final rule, (2) this EQR final rule, and (3) the EQR protocols developed in response to the BBA statutory requirement. The QISMC document has been superseded by these three documents for the purposes of Medicaid. Each of these documents is accompanied by text describing how they should be integrated into State quality improvement systems.

Comment: One commenter contended that the proposed rule significantly reduced State flexibility in defining the content and cycle of EQR, exacerbated what the commenter considered a double standard for quality oversight between Medicaid FFS and Medicaid managed care, and placed new requirements on States not previously required of managed care programs. The commenter was concerned that this rule would create another reason to discourage MCOs and potentially PIHPs (especially those that provide behavioral health services) from participating in Medicaid resulting in fewer managed care options for Medicaid agencies and beneficiaries.

Response: We do not agree that this regulation significantly reduces State flexibility. EQR is not a new requirement on States. EQR has been a requirement for States contracting with MCOs since section 1902(a)(30)(C) of the Act was enacted in OBRA 1986. The BBA introduced new requirements for EQR and provided parameters we are obligated to follow in developing this regulation. The new requirement in section 1932(c)(2)(A)(iii) of the Act that protocols be developed which must be followed by States necessarily limits State flexibility to some extent. However, we believe that we have provided appropriate flexibility in implementing this statutory requirement. To do this, in collaboration with an expert panel that included State participants, we defined what activities we considered to be essential for an EQR. The statute also requires that EQR be conducted annually. While flexibility as the nature of review under EQR may have been limited somewhat by the requirement in section 1932(c)(2)(a)(iii) of the Act that protocols be followed, the new rule provides States with substantial new flexibility by allowing an expansion of the types of entities with which States can contract to conduct EQR activities, and extends the 75 percent match rate to these types of entities. In addition, this final rule allows a State to conduct EQR-related activities itself or through other State contractors. Thus, we do not believe that this rule will discourage managed care contracting.

Comment: One commenter expressed concern that the rule will limit a State's ability to maintain and improve distinct State quality initiatives due to more extensive Federal quality improvement initiatives. Specifically, the commenter believes the rule would require States to either externalize or duplicate ongoing State quality improvement activities.

Response: We do not believe that these EQR requirements will result in a duplication of any ongoing State quality improvement activities. A State may conduct any of the EQR-related activities internally or through other State contractors. The State will need to conduct the activities using our protocols or protocols consistent with ours if the information is to be used as part of the EQR. Therefore, at a minimum, our protocols or protocols consistent with ours must be used for the mandatory activities. As stated earlier, the protocols are generic instructions to ensure that the activities are conducted in a methodologically sound manner. If a State chooses to conduct EQR activities internally or have a State contractor other than the EQRO conduct the activities, the State expenses will be matched at 50 percent. States must contract with an EQRO for only one function, that is for the analysis and evaluation of the aggregated information provided from the EQR activities and the development of the EQR results. States can also continue to conduct other quality initiatives outside of the scope of EQR and claim the 50 percent administrative match.

Comment: One commenter contended that the proposed rule exceeded our statutory authority. Specifically, the commenter argued that with this rule, we effectively assumed control of a State's quality assessment and performance improvement strategy by specifying (1) the details of QI activities through detailed protocols developed without input from individual States, and (2) which activities can be performed by a State government entity, and which must be delegated to the EQRO. The commenter recommended that the proposed rule be withdrawn and redrafted to: (1) Allow for public review and comment of the protocols, and (2) permit States to carry out their statutory responsibilities as reflected in section 1932 (c)(1)(A) of the Act. The commenter also doubted that uniformity of EQR results could be accomplished in light of State programs that demand custom-tailored management and oversight models.

Response: We do not agree that we have exceeded our statutory authority in developing this regulation. The statute clearly required us to develop protocols to be used in the external review. We developed the protocols, as mandated, through an independent quality review organization with the guidance of an expert panel that included State representation, as required by the statute. A **Federal Register** notice announcing the completion of the protocols was published on November 23, 2001 (66 FR 58741). In that notice, we asked for comment on the extent to which burdens were imposed by the protocols, or on any other aspect of the protocols. Comments received from that solicitation, and our responses, are included in the preamble to this final rule.

We also believe we have provided significant flexibility to States as to which activities must be performed by an EQRO, as the only activity that must be conducted by the EQRO is the analysis and evaluation of the aggregated information produced from the EQR activities, and production of the results of that review as defined in § 438.364. The State can conduct the mandatory EQR-related activities, or have another State contractor conduct these activities, as long as the State uses our protocols or protocols consistent with ours.

Comment: One commenter believed that the EQR activities in the proposed rule were duplicative of the scope of work required in Independent External Evaluations of waivers under section 1915(b) of the Act, and recommended that the proposed rule be withdrawn until we develop a unified, coordinated approach to waiver oversight.

Response: The EQR activities in this rule are not duplicative of activities conducted as a part of independent assessments under section 1915(b) of the Act. The independent assessment requirement is a review of a State's mandatory managed care program under the authority of section 1915(b) of the Act. It reviews how adequately a State ensures access to quality services in the mandatory managed care waiver program, and the costs of the waiver program. The unit of analysis of the

independent assessment under section 1915(b) of the Act is the State's managed care program as a whole, not individual MCOs or PIHPs. In contrast, the EQR review is a review of individual MCOs and PIHPs. The EQR requirement applies to all MCOs and PIHPs regardless of whether the program is voluntary or mandatory or whether it is authorized under a waiver. Further, EQR is conducted annually, whereas the review under section 1915(b) of the Act is conducted for the first 2-year period of the waiver, and the first renewal period (assuming the review results are acceptable). In addition, the independent assessment that we require in the case of a waiver under section 1915(b) of the Act applies to PCCM programs as well as programs with capitated arrangements. The EQR requirement does not apply to PCCM programs.

Comments: One commenter supported the proposed elimination of the requirement in § 434.53 for a system of periodic medical audits.

Response: While we note that this comment does not directly pertain to this proposed rule, we agree with the commenter. We believe that the system of periodic medical audits under § 434.53 is an out-dated approach to quality assessment and improvement which would be duplicative of EQR activities. (In this sense, the matter is relevant to this final rule.) Consequently, the Medicaid managed care final rule published on June 14, 2002 eliminated this requirement, as well as other regulations in subpart E of part 434.

Comment: Several commenters thought the proposed time period for bringing contracts into compliance with the new EQR requirements did not provide sufficient time for States. One commenter suggested that the new EQR rules apply to contracts entered into or revised on or after 90 days, but no longer than 18 months from the effective date. One commenter believed that States needed more than a year to implement this rule. One commenter recommended implementation of the redrafted rule on January 1 to be consistent with NCQA and other planning cycles and allow up to 180 days before implementation.

Response: To be consistent with the Medicaid managed care final rule, we have retained the effective date of this rule to be 60 days following its publication. However, we have revised the time frame for provisions to be implemented through contracts with MCOs, PIHPs, and EQROs so that they must be effective with contracts entered into or revised on or after 60 days following the publication date. States have up until no longer than 12 months from the effective date to bring contacts into compliance with the final rule provisions.

M. Collection of Information Requirements: December 1, 1999 Proposed Rule

In the December 1, 1999 proposed rule, we asked for comment on the following provisions that contain information collection requirements: nonduplication of mandatory activities (§ 438.360), exemption from external quality review (§ 438.362), and external quality review results (§ 438.364).

A. General Comments

Comment: One commenter contended that the burden to the MCO of working with the EQRO is not included.

Response: As part of the MCO and PIHP contracts with States, MCOs and PIHPs are required to work with States on a routine basis. This includes working with State contractors. We do not believe that working with EQROs adds burden for MCOs and PIHPs but continue to believe that it is part of the normal course of business for MCOs and PIHPs with Medicaid contracts. Further, a requirement for EQR is not new. It has been in place since the late 1980's under section 1902(a)(30)(C) of the Act.

Comment: One commenter felt that while the financial impact of this rule may be difficult to quantify, the proposed regulations would significantly increase the time and administrative burden on States, EQROs, MCOs, and PHPs well beyond the hourly estimates in the preamble.

Response: We do not agree that the regulation will significantly increase the time and administrative burden of States, EQROs, MCOs, and PIHPs beyond what we estimated in the proposed rule. Through our data and information collection, we know that the EQR-related activities referenced in this rule are those that are already typically required by States. Similarly, MCOs have previously been complying with EQR requirements subsequent to the enactment of section 1902(a)(30)(C) of the Act in 1986.

Section 438.360 Nonduplication of Mandatory Activities

Comment: Several commenters argued that the estimate of the total burden for the State for the proposed nonduplication provisions was too low, and asked how the estimate of 4 hours was determined. One commenter asked what data the MCO would need to provide to the State under proposed § 438.360(b)(2) and (c)(2).

Response: We estimated that it would take State staff approximately 4 hours to collect, copy, and disseminate the reports, findings, and other results of Medicare reviews or information obtained from the accreditation reviews and sent to the State. Because we received several comments indicating that this estimate was low, but commenters did not provide us with what they believe the estimate to be, we have increased the burden hours by 100 percent, to 8 hours. In accordance with § 438.360(b)(3) of the final rule, the MCO or PIHP needs to provide to the State any reports, findings, or results from an accreditation review or our review for Medicare for the standards in § 438.204(g) that are being substituted in place of a Medicaid review. In addition, if the MCO or PIHP provides services to dually eligible individuals and the State allows the MCO or PIHP to provide information from a Medicare review of performance measures and performance improvement projects for the EQR in place of separate Medicaid measures and projects, under § 438.360(c)(3), the MCO or PIHP will need to provide the results of Medicare review activities to the State.

Section 438.362 Exemption From External Quality Review

We did not receive any comments on the information collection burdens associated with complying with this provision.

Section 438.364 External Quality Review Results

Comment: One commenter noted that the preamble of the proposed rule addresses the burden of disseminating information, but not of creating the content listed. The commenter believed that the burden for creating the information required to comply with § 438.364(a)(2) would be significant, and would serve no purpose other than to comply with the rule. The commenter recommended deleting § 438.364(a)(2). Several commenters argued that the effort to compile and aggregate the data, analyze, and formulate the review reports will take a significant number of hours above the estimated number.

Response: The proposed rule did not address the burden of conducting EQR activities, because we had not completed the protocols at the time the proposed rule was published. A request for comment on the information collection requirement burden of the protocols was solicited in our November 23, 2001 **Federal Register** notice. We did, however, address in the proposed rule the burden associated with creating the EQR results report. We estimated

that it would take 160 hours for an EQRO to prepare and submit the EQR results. Since we received several comments stating that it would take more time than the 160 hours we proposed, but commenters did not provide us with time estimates, we are increasing the burden hours by 25 percent.

We do not agree that the burden of § 438.364(a)(2) is significant, or that it serves no useful purpose. We believe that an assessment of the strengths and weaknesses of MCOs and PIHP performance as it relates to the quality, timeliness, and access to health care services was the intent of the statutory provision that requires the results of EQR be made available to beneficiaries and providers. We retain these EQR results provisions in the final rule.

N. Impact Statement

To comply with Executive order 12866 and the Regulatory Flexibility Act we examined the impact of the December 1, 1999 proposed rule. We determined that the net impact of the proposed rule would be below the $100 million annual threshold, and that a regulatory impact analysis was, therefore, not required.

Comment: Several commenters believed that the proposed rule would result in greater costs and burden to States and MCOs than we estimated in the impact statement. The commenters stated that we did not estimate the increased costs to States and MCOs for external review for compliance with standards. The commenter also felt that we did not consider the negative impact of external auditing on other MCO activities, or new and ongoing infrastructure and labor, needed to comply with these provisions. One commenter contended that these activities would require MCOs and their providers to devote significant staff time to collect, organize, and prepare for review of large quantities of quality assurance data. Another commenter felt that due to the independence requirements, the net results would be that fewer entities would qualify to conduct EQR.

Response: We do not agree with these comments. The only activity that must be conducted by an EQRO is the analysis and evaluation of the information obtained from the EQR activities. If a State chooses to, it can conduct any of the EQR-related activities and receive the 50 percent administrative match as long as the activities are conducted using our protocols or protocols consistent with those we developed. In addition, many States are already conducting or having State contractors conduct many of the EQR activities. As we stated in our proposed rule, most States are already obtaining a 75 percent matching rate for many of these activities and we, therefore, believe there will not be a significant increase in Medicaid expenditures, and that no new significant infrastructure will be needed. We do not believe that this requirement will cause MCOs to devote significantly more time to collect, organize, and prepare for EQR than is already required by States to ensure compliance with their contracts with MCOs and PIHPs.

Because this will be a new requirement on PIHPs, we acknowledged in the proposed rule that there may be additional cost to the Federal government, since States currently conducting these activities receive a 50 percent administrative match, but under this rule they can now obtain the enhanced 75 percent FFP. We do not believe these costs are significant. Based on an analysis of 2001 Quality Improvement Organization funding on the CMS–64, we estimate a cost of $5,800,000.

Comment: One commenter, while supportive of holding MCOs accountable by measuring quality of care, noted that there is no such requirement for the Medicaid FFS program, and that these costs are, therefore, not reflected in the rate-setting methodology for managed care plans. This commenter also noted that undertaking these reviews has a significant cost implication for both the MCOs and the State.

Response: The statutory quality assessment provisions implemented in this final rule do not apply to the Medicaid FFS program. Moreover, there is no statutory or legislative history to indicate that the Congress intended that these provisions should apply to Medicaid FFS. The Collection of Information Requirements and Impact Statement address what we believe to be the cost implications of this requirement as it pertains to Medicaid capitated programs. We note that in the Medicaid managed care final rule, a new methodology was adopted for setting capitation rates. This methodology permits States to reflect MCO and PIHP administrative costs (including costs of complying with quality assessment requirements that do not apply under FFS Medicaid) in capitation rates.

Comment: One commenter believed that requiring an independent organization to conduct a review of an MCO's structural and operational standards would add an additional administrative expense to the program.

Response: States currently review MCOs and PIHPs for compliance with State standards. If conducted by the State, this expense is reimbursed at a 50 percent administrative match. However, some States currently define this activity as part of EQR, and thus receive the 75 percent enhanced Federal match. Under the provisions of this rule, if a State chooses to contract with an EQRO to conduct a review of MCO and PIHP compliance with State standards, a State can obtain a 75 percent enhanced match rate. While this may increase Federal expenditures, we do not believe that the increase will be significant, as some States already have their EQROs conduct this activity. Thus, we do not believe this affects our conclusions regarding the need for a regulatory impact analysis.

Comment: One commenter believed that the proposed reporting requirement would increase costs.

Response: States currently have their EQROs develop reports. We believe that this will not add significantly to the current costs incurred by the Medicaid program.

Comment: One commenter believed that our proposed decision to extend EQR requirements to PHPs would increase costs to States, and that we have not fully analyzed this financial impact.

Response: We stated in our proposed rule that applying this provision to PHPs might result in additional costs. Although States are currently conducting a variety of quality activities with their PIHPs and receiving a 50 percent administrative match for their costs, they now may obtain the enhanced 75 percent FFP match for these activities. Again, while this will result in some additional Federal costs, State costs will decline. We do not believe these costs are significant. As stated in a previous response, based on an analysis of 2001 Quality Improvement Organization funding from the CMS–64, we estimate a cost of $5,800,000.

Comment: One commenter was concerned about the cost of responding to additional EQR requirements, and the potential for duplication and administrative burden to comply with QISMC, the Medicaid rules, and EQR rules.

Response: We do not foresee that there will be any duplication of effort between complying with the BBA provisions, including the EQR provisions, and QISMC. As we stated previously, QISMC has been superseded by the Medicaid managed care final rules that incorporate key elements of the QISMC document.

III. Collection of Information Requirements: November 23, 2001 Federal Register Notice: Discussion of Public Comments

Many of the comments we received in response to the November 23, 2001 **Federal Register** notice were issues pertaining to the December 1, 1999 proposed rule, as opposed to collection of information requirements or other issues concerning the protocols. Most of those issues were addressed in the previous section that responded to comments received on the December 1, 1999 proposed rule. This section addresses comments related to the burden estimates and any other aspect of the collection of information. We believe that burden estimates apply to the following sections of the regulation: EQR protocols (§ 438.352), Nonduplication of mandatory activities (§ 438.360), Exemption from EQR (§ 438.362), and EQR results (§ 438.364). We first address general comments.

A. General Comments

Comment: Several commenters did not agree with the methodology we used to estimate costs associated with implementing EQR. One commenter believes the methodology is flawed and our projected costs may be significantly lower than actual costs because our sample was too small and the range of estimates is too large for cost averaging. The commenter is also concerned that the methodology does not account for indirect costs such as rent, transportation, and medical record photocopies. The commenter recommended that indirect costs that account for geographic variation should be added to accurately predict the cost of using the protocols. One commenter stated that our approach did not include a determination of whether the function performed by the sampled EQROs approximated the functions that would need to be conducted in accordance with the protocols. The commenter further noted that because we estimated a range of hours for conducting EQR-related activities, we have not provided a representative assessment of the burden to perform the EQR activities. The commenter recommended we develop a more accurate projection of hours and costs associated with performing these activities consistent with the protocols.

Response: While the actual number of EQROs we interviewed was relatively small, as stated in our November 23, 2001 **Federal Register** notice, these EQROs had reviewed 16 managed care programs in 8 States (Arizona, California, the District of Columbia, Maryland, New Mexico, Nevada, Tennessee, and West Virginia). Each of these States contract with a different number of MCOs to provide Medicaid services, ranging from States contracting with a few MCOs to States with several dozen MCOs. So, even though the number of EQROs we interviewed was small, we believe we chose EQROs that represented a broad range of experience in terms of the number of MCOs they review, as well as representing an adequate geographic mix.

We also recognize that using a broad range of hours given by the interviewed EQROs to estimate the average number of hours it will take to conduct each activity may overestimate or underestimate the actual costs. However, by showing the ranges of costs we averaged, we show the variability across States that are inherent when conducting quality review activities. As stated above, we believe the interviewed EQROs represent an adequate number of MCOs reviewed. In addition, even though we did not specifically ask each EQRO about the methodology that they used to conduct the EQR activities, the protocols represent generic activities and steps that are followed in both the public and private sector. We, therefore, believe that the activities for which we collected cost information were conducted using a methodology consistent with our protocols. Moreover, we have no reason to believe that the interviewed EQROs' estimates provided did not include indirect costs for conducting EQR activities. Because the commenters did not suggest a specific methodology or what other data should be used in such a methodology, we retain the methodology used in the November 23, 2001 **Federal Register** notice. We have updated the estimates based on more current data on the number of MCOs and PIHPs contracting with State Medicaid agencies to provide services to Medicaid beneficiaries.

Comment: One commenter objected to our not including the time necessary for MCOs to collect and submit the information necessary to perform the functions identified under § 438.358, activities related to EQR. The commenter recommended that we interview health plans to determine the estimates for this activity and include them in our analysis.

Response: We agree with the commenter and include burden estimates in this final rule to address the time and costs associated with MCO and PIHP submission of information necessary for the validation of performance measures, validation of performance improvement projects, and a review for compliance with structural and operational standards. The protocols for all three of these activities require that documentation be provided by the MCO or PIHP. We do not anticipate, however, that new documentation will need to be developed. For example, the documentation review activity that occurs when a review for compliance with standards is conducted includes a review of reports, policies, and surveys that already exist. We believe that it will take each MCO or PIHP approximately 4 weeks of one full-time equivalent employee to prepare the information to be submitted for the three mandatory activities and we have added this estimate under § 438.352, the EQR protocols.

Comment: Two commenters believe the protocols will result in significant burdens in the areas of data collection, duplication of management oversight, and financial costs to the State and its contracting MCOs. One commenter estimated the new costs associated with the three mandatory activities and the overall EQR will be an additional $250,000 per MCO. Another commenter believes the cost per MCO would be approximately $424,000 for the three mandatory activities. The commenters noted there will be additional indirect cost incurred by the State to administer and oversee the EQRO contracts, and by the MCOs associated with the annual preparation for the three mandatory activities.

Response: We do not agree that the protocols will cause significant financial costs to MCOs and States, cause significant burdens in the areas of data collection, or duplicate other oversight activities. Many States already require their contracting MCOs and PIHPs to conduct performance improvement projects, calculate performance measures, and comply with State standards. The three mandatory activities that ensure compliance with these requirements are also already conducted by many States. However, States may not be contracting with their EQRO for the conduct of all these activities. As stated earlier in this preamble, the State can conduct these activities itself or contract with an EQRO or other entity for the conduct of the EQR-related activities. If the State contracts with an EQRO, it will receive the enhanced 75 percent FFP. If States are not currently contracting with their EQROs for these activities and decide to contract with their EQRO for EQR-related activities under this authority, it will decrease their costs related to quality activities, as opposed to increasing their costs.

We believe that the EQR mandatory activities can easily be incorporated into existing State quality assessment systems and will not duplicate existing oversight activities. The conduct of EQR and the conduct of EQR-related activities is required as part of the quality strategy under § 438.204 of the Medicaid managed care final rule and MCO quality assessment and performance improvement program requirements under § 438.240 of the Medicaid managed care final rule. Furthermore, we believe that there will not be additional costs incurred by the State to administer and oversee the EQRO contracts since this is already an existing requirement on States and MCOs under OBRA 1986. Because the commenters did not provide us with an alternative methodology to use or evidence to support their statement, we retain the approach taken in the November 23, 2001 **Federal Register** notice on the information collection requirements and in the impact statement in the December 1, 1999 proposed rule.

Comment: One commenter disagreed with our assumption that the implementation of EQR would not have an increased cost to the Federal government. The commenter did not agree that the costs incurred with current EQR activities are representative of costs that would be incurred under the new requirement. The commenter argued that States currently contract with EQROs for a more limited scope of activities.

Response: Our December 1, 1999 proposed rule acknowledged that there is likely to be an increase in Federal expenditures but that we did not anticipate this to be a significant increase. We agree with the commenter that the scope of work may be different under the BBA EQR requirements than it was under the OBRA 1986 requirements. However, we do not believe that the cost difference will be significant and it is likely that there could be a decrease. By expanding the pool of organizations available to conduct EQR, State agencies may be able to negotiate savings. We also hope that additional savings will be realized through opportunities afforded by this rule to coordinate EQR activities with other quality and oversight activities.

As stated in our December 1, 1999 proposed rule, we expect some increase in expenditures since we are applying the EQR requirement to PIHPs. We do not expect this to be a significant increase in expenditures because States already conduct quality review activities on PIHPs and receive a 50 percent FFP. Now States will be able to qualify for the enhanced 75 percent FFP.

Section 438.352 EQR Protocols—General Comments

Comment: One commenter believes the scope of the protocols could result in excessive burdens and they should be revised.

Response: For several reasons, we do not agree that the scope of the protocols will result in excessive burdens. First, all protocols are based on procedures already in use in the private sector. These protocols, therefore, are consistent with common industry practice in widespread use today. Second, many States and MCOs and PIHPs are already conducting these activities, using methods consistent with or more intensive than the activities and steps found in these protocols. For example, many State agencies are using the CAHPS surveys. The protocols for administering these surveys are consistent with our survey protocol, but much more prescriptive. Similarly, many States are also requiring validation of performance measures or encounter data using approaches consistent with these protocols. Third, the States have the option to use the protocols we developed or protocols consistent with ours. The protocols also include sample worksheets that can be used or modified at the State's discretion. Fourth, we note that States are only required to use three of the nine protocols that we have developed; the other six protocols are developed for optional activities that States can choose to undertake or not, at their discretion. For these reasons, we believe the protocols will not be excessively burdensome, and we retain the scope of the protocols as introduced through the November 23, 2001 **Federal Register** notice.

Comment: One commenter recommended that there be a better explanation of the use and purpose of the protocols.

Response: Section 1932 (c)(2)(iii) of the Act required us, in coordination with NGA, to contract with an independent quality review organization to develop protocols to be used as part of EQR. The purpose of the protocols is to provide EQROs with a set of generic instructions that ensure that EQR activities are conducted using sound methodological principles. To provide ongoing explanation about the use of the protocols, we have created a Web site at *http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp* that presents the protocols and an explanation of their intended use.

Comment: One commenter recommended that we not base the protocols on Federal or industry guidelines and standards, but that we incorporate these standards by reference.

Response: We disagree with the commenter. We purposefully directed our contractor to develop the protocols following protocols and quality review activities currently used in the managed care and quality oversight industries. We believe it is important to take advantage of the knowledge and experience that exists in the Medicare program and the private sector. Consistency with these approaches will also minimize the burden of complying with the protocols.

Comment: One commenter believes that the activities in this protocol will result in the State agency becoming the accrediting agency for Medicaid managed care, increasing the scope of prescribing and monitoring necessary by the State.

Response: We disagree with the commenter. The purpose of the three mandatory EQR-related activities is to ensure that MCOs and PIHPs are in compliance with §§ 438.204(g) and 438.240 of the Medicaid managed care final rule. However, many States currently conduct these activities. States that do not currently monitor for compliance with quality standards, monitor MCO and PIHP quality improvement projects or require the calculation of performance measures will need to initiate these activities. We believe that monitoring for these activities is consistent with the intent of the BBA EQR statutory provision to ensure that MCOs and PIHPs are providing access to timely and quality services.

Comment: One commenter believes the protocols are very clear in describing what information needs to be collected.

Response: We agree with the commenter and retain the activities and steps in the protocols introduced through the November 23, 2001 **Federal Register** notice.

Comment: One commenter believes that the protocols lack an evidenced-based approach to quality improvement. Another commenter believes that measuring MCO performance should be oriented to empirical performance outcomes and applied against quantifiable baselines and benchmarks rather than determining compliance through document reviews and interviews.

Response: We disagree with the first commenter. As we explained above, these protocols were developed

consistent with protocols and quality review activities currently used in the managed care and quality oversight industries. Further, the protocols addressing performance improvement projects explicitly incorporate provisions addressing the use of clinical and nonclinical evidence in the selection of quality indicators. We agree with the second commenter that MCO and PIHP performance should be oriented towards performance outcomes that are measured against baselines and benchmarks. This is one reason why the information obtained from the validation of performance measures and the validation of performance projects is to be included as part of the EQR function. We also believe however, that a review of the MCO's and PIHP's compliance with State standards is essential for determining whether access to quality and timely services is provided. We believe this information used in conjunction with the information obtained from the validation of performance measures and performance improvement projects provides for both a qualitative and quantitative approach to assessing MCO and PIHP performance.

Comment: One commenter recommended that specific clinical areas (for example, early and periodic screening, diagnosis, and treatment (EPSDT) reporting) be addressed in multiple protocols.

Response: We believe that a variety of both clinical and nonclinical areas of care need to be assessed by the State and MCO or PIHP over time. However, we do not specify in regulation or in our protocols what those specific clinical and nonclinical areas should be because we believe that States should have the discretion to identify priority topics based on their knowledge of the public health priorities in the State, the health care needs of their beneficiaries, and based on discussions with beneficiaries and other stakeholders in the State. If we do decide that it is necessary to identify national priority topics, § 438.240(a)(2) of the Medicaid managed care final rule provides us with the authority to do so in consultation with States and other stakeholders.

Comment: One commenter asked that the protocols reflect our review criteria for children with special needs.

Response: When States require children with special health care needs to enroll in a capitated Medicaid managed care program, they must follow the review criteria provided in the January 19, 2001 State Medicaid Directors' letter. The Medicaid managed care final rule includes standards States must comply with when contracting with MCOs and PIHPs that enroll Medicaid beneficiaries, including children with special health care needs. These standards address the principles on which the review criteria are based. This protocol does not put forth any new standards, but identifies methods to determine compliance with current standards.

Comment: One commenter suggested that the protocols require the validation of performance measures submitted by MCOs, unless the measures were validated by a reliable entity using comparable standards.

Response: If performance measures are validated by an entity using an approach consistent with our protocol, only the information obtained from that review needs to be provided to the EQRO to be used as part of the EQR function. The review activity itself need not be duplicated. In addition, if the entity qualifies as an EQRO, the State can capture the enhanced 75 percent Federal match.

Comment: One commenter recommended that assessments of quality should include multiple sources of information including audits, certifications of sufficient networks and systems, and other submissions the MCO has provided to the State outside of the review process.

Response: We agree with the commenter that information from multiple sources should be included as part of the EQR. We believe we have accomplished this through the multipronged approach we have provided for in this final rule. The EQR will include information from the validation of performance improvement projects, the validation of performance measures, and a review for compliance with standards that may include plan network adequacy information, service authorization procedures, and other documentation that attests to the structural and operational components of the MCO or PIHP.

B. Protocol for Determining Compliance With Structural and Operational Standards

1. General Comments

Comment: The commenter believes that because we used a combination of private sector protocols in the development of the protocol for compliance with structural and operational standards, our protocol is likely to be more burdensome than that of any one private sector protocol.

Response: We reviewed a number of private sector protocols in the development of the protocol for compliance with structural and operational standards. We identified those elements common to all and used those as a basis for the protocol. Our protocol is not an additive combination of private sector protocols. Conversely, it is a synthesis or a streamlining of common elements found in multiple private sector protocols. Consequently, we do not believe our protocol is more burdensome than any one private sector protocol.

Comment: One commenter argued that CMS, for Medicare, is changing its onsite review process so this will be less frequent and more targeted. Medicare is also streamlining its review guide and will be reviewing less documentation and including more self-auditing by MCOs. The commenter recommended that we adopt a similar approach.

Response: The process for how this protocol will be used is set forth in this final rule, which contains provision for less frequent monitoring, and under certain circumstances, for the nonduplication of activities conducted under the Medicare program reviews or independent accreditation surveys. Through these regulatory provisions, we believe we have adopted a streamlined approach to quality review, similar to that used by Medicare.

Comment: One commenter is concerned that this protocol requires intensive onsite reviews to determine compliance with the structural and operational standards required in the Medicaid managed care final rule. The commenter believes that to meet the goals of EQR, it is not necessary to include all the areas identified in the monitoring protocol and that States should not be required to use this approach. One commenter believes that the guidance on the onsite review process is prescriptive and it is unlikely that the EQRO will need or use this detailed level of guidance. In general, the commenter believes the protocol is overly detailed and should be simplified to examine major structural and process requirements.

Response: The degree to which the protocol relies upon onsite reviews is consistent with the degree to which onsite review is used by private accrediting bodies. Therefore, we do not believe the onsite review specified in our protocol is too intensive. In the private sector, when an accrediting body has a standard, they monitor for compliance with it through a combination of interview activities and document review. We have followed this private sector approach and intend that all Federal requirements be monitored for compliance. Because the protocol contains only ''potential'' interview questions and documents for

''potential'' review, States, in using the protocol, will be able to target the reviews as they determine appropriate. We believe the protocol provides an appropriate amount of detail needed to reflect the scope and depth of the quality review activities to be conducted. We note in the protocol that, although the EQR activities must be consistent with the protocol, they need not be identical, thus providing the option for the States to prescribe a less detailed level of activity to the EQRO.

Comment: One commenter recommended that documents be obtained in advance and that multiple fact-finding efforts occur over time before conducting the onsite reviews. This allows State staff to be better prepared and is less disruptive for MCO staff.

Response: The EQR protocols are designed for use by EQROs which in many circumstances are not likely to be staffed by State personnel. However, State staff conducting compliance reviews may also use the protocols at their discretion. The protocols specify that documents may be obtained in advance, and reviewers, though not directed to do so, are not precluded from performing these activities over time.

Comment: One commenter recommended that the protocol include the review of previous monitoring reports and that the MCO's efforts and progress in correcting past problems be noted.

Response: We agree with the commenter. Therefore, in the final protocol, we have added that, before the onsite visit, reports on previous reviews and subsequent MCO and PIHP corrective actions be reviewed to identify areas on which the EQRO might need to focus the current monitoring activities.

Comment: One commenter recommended that the protocol include a mechanism for the State to prepare and submit oversight findings to the MCO and approaches to follow-up to ensure that corrective action has occurred. The commenter also recommended that every onsite review end with an exit interview to focus the MCO's attention on those areas the State is concerned about and intends to address in the findings and recommendations report.

Response: We agree with the commenter that evaluation results need to be reported to the MCO or PIHP. This reporting is common practice upon completion of a performance evaluation and a number of strategies are available for this reporting. We describe four possible alternatives for reporting in the protocol, but States are not precluded from selecting other alternatives that might include exit interviews with the MCO or PIHP at the conclusion of the onsite review.

Comment: One commenter recommended simplifying the compliance scoring system and placing greater emphasis on objective indicators of organizational performance such as performance improvement projects and survey results.

Response: We agree that other sources of information may provide information pertaining to MCO/PIHP compliance with the regulatory provisions, and we list some of these sources in the protocol under Activity 5, ''Collecting Accessory Information.'' In defining regulatory compliance, we have indicated that the State Medicaid agency will need to identify the level of compliance it requires and what rating or scoring system is to be used. In the protocol, we offer examples of common approaches, but because there is no evidence that one scoring system is better than all others, we allow States the discretion to select the scoring system to be used.

Comment: One commenter believes that of the four alternatives listed in the protocol for reporting evaluation results to the State Medicaid agency, neither the first nor the fourth alternative is acceptable. The commenter claims the first alternative makes information vital to the review; that is, the reviewers' analysis, unavailable to the State, while the fourth alternative represents a complete delegation of the State's monitoring responsibility to the EQRO.

Response: We do not agree with the commenter. In the first alternative, analysis is guaranteed based upon the definition of EQR in this final rule. According to that definition, EQR requires ''the analysis and evaluation of aggregated information.'' In the fourth alternative, reporting is accomplished based on pre-established State thresholds and guidelines, and therefore does not represent a complete delegation of the State's monitoring responsibility to the EQRO. The four alternatives listed in the protocol are possible scoring strategies; we state in the protocol that other options are available for use by States.

Comment: One commenter recommended that States require EQROs to use a standard written reporting tool.

Response: We agree with the commenter and have included a sample document and reporting tool (Appendix C, Attachment C of the final protocol) for this purpose. However, we allow States to modify this sample tool or develop another standard reporting tool, at their discretion.

Comment: One commenter noted that many questions are broad and not well written so the nature of the response being sought is unclear. The commenter recommended that the entire section for interviews should be reviewed in the context of whether the EQR rule is being exceeded by the data required during the interviews. Several commenters recommended that the interview section be dramatically shortened by eliminating duplicate questions and by deleting questions whose answers cannot be evaluated against the State's MCO contract specifications or a specific provision in the rule.

Response: We do not agree that we should more narrowly construct or abbreviate the interview questions. We have included a range of potential interview questions related to the subject matter of the regulatory provisions for reviewer use in prompting discussion. We expect, in practice, the reviewers will customize the interviews as necessary to clarify issues and confirm document findings. In the protocol, we compiled questions related to the regulatory provisions for each group of interview participants; for example, MCO or PIHP leadership, enrollee services staff. While this format creates some redundancy among the interview groups, we believe it facilitates the interviews by enabling each interview group's questions to stand alone. We also note that it is common practice in private accreditation reviews to ask the same or similar questions of different MCO or PIHP staff and also to review documents to support information obtained from interviews to determine if the information obtained from multiple sources converges and reaffirms the EQROs conclusions.

Comment: One commenter believes the protocols are bureaucratic and administratively burdensome and that there is a lack of evidence of the success of this type of process-oriented oversight. The commenter further stated that the level of detail is excessive to ensure conformance with MCO contracts and the BBA rule, and that the purpose is not for an accreditation.

Response: The protocols are based upon the common elements found in compliance protocols used by private sector accrediting bodies and the Medicare program. Consequently, we do not believe they are overly bureaucratic, administratively burdensome, or without a sound evidentiary basis. We also have followed the private sector approach in specifying that all standards, in this case the Federal

requirements, be monitored for compliance. We believe the protocol provides an appropriate amount of detail needed to reflect the scope and depth of the quality review activities to be conducted. We note again that the specific interview questions are suggestions only, and we expect the questions to be customized for each review.

Comment: One commenter claimed that some informational items the EQRO is to collect from the State Medicaid agency do not exist as contract provisions and may not exist as other standard documents. This will create additional paperwork. The commenter recommended that the EQRO should only verify that the State's managed care contracts require compliance with applicable State and Federal laws.

Response: We do not agree with the commenter. The background information that the EQRO will need to collect from the State under this protocol includes written documentation of those standards, requirements, or decisions pertaining to MCOs and PIHPs that the State established to comply with the regulatory requirements that implement the BBA provisions governing standards for contracts with MCOs and PIHPs. This information is needed to assess MCO or PIHP compliance with those regulatory provisions for which the State is required to establish certain standards.

Comment: One commenter claimed that the number and types of documents the EQRO is to obtain from the MCO are too extensive and that many of the Code of Federal Regulations citations used to justify the collection of documentation are incorrect and do not relate to the topic. The commenter recommended that the protocol be reviewed for incorrect citations and references and that corrections be made.

Response: We do not agree with the commenter. We believe the documents listed are those needed to evaluate MCO or PIHP compliance with the Medicaid regulatory provisions. The regulatory provisions cited indicate where information obtained from the documents can be applied in the review process. For example, although § 438.214 pertains to credentialing and recredentialing, this provision is applicable to oversight of delegated activities, if the MCO or PIHP delegates credentialing to another entity.

Comment: One commenter recommended that Appendix B to this protocol have a cross-reference table that summarizes each interview question with the respective oversight organization documentation listed.

Response: We believe the format for the protocol itself is generally comparable to the recommended cross-reference table for Appendix B (Attachment B of the final protocol). The protocol includes a table cross-walking the review documentation with the related regulatory provisions. The subsequent interview sections then aggregate the interview questions by regulatory provision for each interview group.

Comment: One commenter was concerned that we do not include information available from consumers as a source of information to be used in this protocol. Several commenters believe this protocol does not go far enough to examine actual practices of MCOs' or beneficiaries' experience with care; rather, it focuses on policies and procedures. One commenter recommended the protocol include interviews with State Medicaid personnel and providers, and input from consumers, consumer advocates, and people with special health care needs.

Response: We agree that providers, consumers, and others mentioned may offer further information about MCO or PIHP performance; however, interviewing these groups requires additional time and substantial resources. Therefore, in this protocol, we have made provider and contractor interviews optional. However, we have further promulgated a separate protocol for the use of provider and consumer surveys as a source of information that can be used for EQR at the option of the State. We believe that mandating additional surveys as a part of this protocol would be burdensome and unnecessary.

Comment: One commenter believes the MCOs can prepare in advance for the review. The commenter recommended reviewers should interview providers and beneficiaries not preselected by the MCOs to ensure compliance with established policies.

Response: We agree with the commenter's concern regarding preselection. For the reasons previously noted, however, provider interviews are an optional part of this protocol. Consumer and provider surveys are also specified as a separate, optional EQR-related activity for securing input from beneficiaries and providers.

Comment: One commenter recommended that among document review and interviews, we include in our approach extensive file review.

Response: We are unsure what files the commenter is proposing for review. The approach used in the protocol is the same approach used by the private sector accrediting bodies and in the Medicare program. If the commenter is referring to medical record review, these are included and discussed in the protocols for validating and conducting performance improvement projects and validating and calculating performance measures.

Comment: One commenter suggested that because a core component of quality programs is responsibility for the program at the highest level of the organization, we include a discussion of committee structure and committee oversight in the overview section.

Response: We assume the commenter is referring to the MCO or PIHP's quality assurance committee and oversight. The protocol addresses compliance with the standards required in the Medicaid managed care final rule. Because committee structure and committee oversight as a core component of quality programs is not included as a standard in the Medicaid managed care final rule, it would not be appropriate to require it in the protocol.

Comment: One commenter believes that the pertinent issue in team development (p. 6 of the protocol) is the identification of the specific functions to be reviewed and the assignment of appropriate personnel to the task, not the size of the team.

Response: We agree that an important consideration in the development of the review team is the determination of the types of personnel appropriate for the review as related to the functions to be reviewed. Therefore, we have specified the desirability of reviewers possessing knowledge of Medicaid and managed care, and experience and familiarity with the regulatory provisions, the evaluation process, and performance expectations.

Comment: One commenter recommended that we include in the list of documents on page 18, committee minutes, vendor oversight committee, and committee structure of the quality program.

Response: The list of documents on page 18 refers to the documents used for determining compliance with specific regulatory provisions. Because the commenter has not stated what regulatory provisions these documents would be used to address, we are unclear as to how to propose their use and have not included them in the document list.

2. Provider/Contractor Services

Comment: One commenter recommended that the review of credentialing files by the EQRO be deleted because the criteria for auditing the files are inadequate. The commenter

recommended that the element be simplified to call for the EQRO to review MCO credentialing policies and procedures for conformance with State contract requirements.

Response: We disagree with the commenter. We believe that a review of policies and procedures alone, when the opportunity exists to review documents providing direct evidence of compliance or noncompliance with the policies and procedures, is a more effective review mechanism. This is consistent with the approach used by private sector accrediting bodies and in the Medicare program.

3. Staff Planning/Education/Development

Comment: One commenter suggested that the requirement for the MCO to produce staff handbooks and information about staff training and orientation be dropped for lack of specificity or rewritten to make clear what criteria the auditors are to use in reviewing the required materials.

Response: We indicate on the list of documents the regulatory provisions to which each document applies. In this instance, staff handbooks and information about staff training and orientation pertain to the requirement that staff be educated about the enrollee's right to receive adequate information; for example, information on disenrollment rights and hearing and appeals. We have specified interview questions for MCO/PIHP leadership, provider and contract services staff, and enrollee services staff concerning how appropriate staff are informed regarding the enrollee right to information. We believe this provides sufficient clarity with respect to the criteria reviewers are looking for and we retain the references to the staff handbook, staff training, and orientation.

Comment: One commenter suggested that the interview questions include probes to determine how staff are trained to comply with Federal and State laws, and how staff advise enrollees of their rights. The commenter recommended further that interview questions address the content, frequency, and thoroughness of the training to confirm no major area of law is overlooked.

Response: We have specified staff handbooks, and orientation and training curriculum, in the list of documents to be reviewed and included interview questions to confirm MCO/PIHP compliance with the regulatory requirements pertaining to enrollee rights and compliance with Federal and State laws. However, if issues arise during the document review concerning the adequacy of the staff's training regarding these provisions, reviewers are directed to explore them during the interviews. We believe this direction affords the reviewers the flexibility necessary to appropriately tailor the review activity. Further, we do not believe it is possible, given the diversity among States and MCO/PIHPs and the scope of the review itself, to include in the list of potential interview questions probes to explore all applicable State laws.

4. Consumer Protections

Comment: One commenter recommended that the protocol include the monitoring of the Medicaid managed care final rule provisions related to consumer protections. The commenter specified for inclusion provisions addressing: the free choice of providers for family planning services (§ 431.51); prohibition on provider discrimination (§ 438.12); availability of out-of-network providers in rural areas (§ 438.52(b)); disenrollment rights as a result of grievance procedures, and related notice and appeal rights (§ 438.56(d) and (f)); enrollee rights regarding treatment, second opinions, and medical record access and correction (§ 438.100); marketing activities (§§ 438.104, 438.700(b)); liability for payment beyond what is legally allowable (§ 438.106); program integrity requirements (§ 438.608); imposition of sanctions (§ 438.700); and multiple charges and denial of services for inability to pay cost sharing (§ 447.53).

Response: We have listed in the protocol documents for review to determine compliance with regulatory provisions related to prohibition on provider discrimination; disenrollment rights as a result of grievance procedures, and related notice and appeal rights (§ 438.56(d)); and enrollee rights regarding treatment, second opinions, and medical record access and correction. We further agree with the commenter and have amended the protocol to include review of the MCO/PIHP's relevant policies and procedures to assess compliance with the regulatory requirements pertaining to the free choice of providers for family planning services; liability for payment beyond what is legally allowable; and multiple charges and denial of services for inability to pay cost sharing. However, the provisions concerning availability of out-of-network providers in rural areas; marketing activities (§ 438.700(b)); program integrity requirements (§ 438.608); and imposition of sanctions (§ 438.700) are responsibilities of the State and not the MCO/PIHP and, therefore, we have not included them as a focus of this protocol. The regulatory requirements in § 438.104, while they pertain to MCO/PIHP marketing activities, are contract requirements that do not directly provide information on quality and are more particular to a State responsibility. Because the protocol is designed to determine MCO/PIHP compliance, we believe it would not be appropriate to monitor these latter activities through the protocol.

5. Enrollee Services

Comment: One commenter believes a State can contract with the MCO to provide information to potential enrollees, and recommends the protocol monitor the MCO's compliance with these informational requirements.

Response: In the August 20, 2001 Medicaid managed care proposed rule, we stated that ''it would be unreasonable to require every MCO/PIHP to provide the relevant information to all potential enrollees.'' We believe the MCO/PIHP should not be contracted by the State to undertake this responsibility, and explained in the proposed rule that ''the State agency is the more appropriate entity to do'' the potential enrollee informing. This requirement was, therefore, not included in our Medicaid managed care final rule and we are not changing the protocol to monitor the MCO's/PIHP's compliance with providing information to potential enrollees.

Comment: One commenter recommended the protocol include a standard reflecting the regulatory requirement for the provision to enrollees of information on services not provided due to moral or religious objections.

Response: We agree with the commenter. The protocol identifies the section of the regulation that requires enrollees to be provided with information about services that are not provided by the MCO or PIHP because of moral or religious objections. It also identifies relevant documents to be reviewed to determine compliance (see pages 22 and 77 of the protocol). These documents include Medicaid enrollee service policies and procedures, statement of enrollee rights, and marketing materials.

Comment: One commenter believes the protocol should include guidance on how to measure the adequacy of the MCO's activities to inform enrollees. The commenter recommends the protocol include additional guidance on the fourth grade reading-level standard for materials, and confirmation that written materials are at an understandable grade level and in

alternative forms to accommodate individuals with sight impairments.

Response: We note that we have provided guidance on this issue in the August 2001 proposed Medicaid managed care rule. In the preamble to the August 2001 proposed rule, we indicated that materials should be understandable to enrollees at a fourth to fifth grade reading level, or at another level established by the State agency that adequately reflects the potential population to be enrolled. Materials should use an easily readable typeface, frequent headings, and should provide short, simple explanations of key concepts. Technical or legal language should be avoided whenever possible. We proposed further that enrollment notices as well as informational and instructional materials relating to enrollment take into account the specific needs of enrollees and potential enrollees, including furnishing information in alternative formats for the visually impaired and for individuals with limited reading proficiency. Also, in 1999, we developed and distributed to the State Medicaid agencies and made available to others a guide entitled, ''Writing and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies.'' The guide was produced to assist States and MCOs/PIHPs in the creation of materials appropriate for their Medicaid populations. We believe the guidance that we have provided in the August 2001 proposed rule and through this guide is appropriate and reflects the current state-of-the-art. Because there is no state-of-the-art standard to apply in measuring the adequacy of the MCO's/PIHP's efforts to inform enrollees, we decline to do so in this protocol.

Comment: One commenter recommended that we monitor the States' definition of what constitutes a ''significant change'' in certain MCO structural and operational features to ensure the State's definition of ''significant change'' is reasonable and fair to enrollees, and that we provide guidance on what parameters a State can use in setting the definitional standards.

Response: The protocol addresses the extent to which an MCO/PIHP, as opposed to the State, complies with the requirements in the Medicaid managed care final rule. Section 438.10(f)(4) of the Medicaid managed care final rule specifies that the definition of ''significant change'' is the State's responsibility. It, therefore, would not be appropriate to include in the protocol the monitoring of the State's definition. Monitoring of States occurs through separate activities conducted by our regional offices. Further, as we stated previously, the protocol is not intended as a mechanism to impose additional quality standards on MCOs/PIHPs or States. Therefore, we do not believe it appropriate to provide guidance in the protocol on what parameters a State can use in setting the definitional standards.

Comment: One commenter noted that the interview questions are good initial probes, but suggested the protocol include additional guidance to more fully probe the MCO's dissemination of enrollee information, and require interviews of providers and enrollees regarding the quality of the informational materials.

Response: We specify in the protocol that reviewers should tailor the interviews as necessary to clarify and confirm document findings. We believe this direction affords the reviewers sufficient flexibility to more fully probe areas as appropriate. Further, we do not believe it is possible, given the diversity among States and MCOs/PIHPs and the scope of the review itself, to include in the list of potential interview questions probes to explore every possible problem or issue that might arise. Provider interviews are time and resource intensive, but because they offer an opportunity to secure additional information regarding MCO/PIHP performance, we have included them as an optional activity if informational needs warrant them and resources permit. We provide for the consideration of enrollee input by including the review of the results of Medicaid beneficiary surveys as accessory information under Activity 5.

Comment: One commenter believes the protocol does not adequately address linguistic issues. The commenter recommended that the review confirm that MCOs collect required language information on enrollees and recognize non-English speakers in all transactions. The commenter suggested further that the protocol include the review of documentation regarding professional translations of written materials, and interviews to assess the quality of the written translations and the MCO's oral interpretation practices and resources.

Response: We believe the protocol does adequately address linguistic issues. In Appendix B (page 79, Attachment B of the final protocol), among the materials to be obtained from the State, we include information on the language(s) that the State Medicaid agency has determined are prevalent in the MCO's/PIHP's geographic service area. On page 85, we direct the reviewer to look at marketing, enrollment and other informational and instructional materials relating to enrollment, enrollee handbooks, new enrollee materials, statements of enrollee rights, and other written materials routinely prepared for Medicaid enrollees and potential enrollees to determine whether these materials are available in the language(s) that have been identified as prevalent within the MCO/PIHP's particular service area. Further, the Medicaid managed care final rule at § 438.204(b)(2) requires States to identify the primary language spoken by each Medicaid enrollee and provide this information to the MCO/PIHP at the time of enrollment. Finally, we believe requiring EQRO re-review of translated materials is more burdensome than appropriate and therefore have not included it in the protocol.

6. Enrollee-Provider Communication

Comment: One commenter objected to the implication that by contract MCOs may place limits on providers' communication with enrollees about reproductive health services. The commenter recommended that the protocol include document review and interview questions to address whether reproductive health services are provided and whether restrictions are placed on provider communication. The commenter suggested further that for MCOs that exclude any reproductive health services the State monitor enrollee access to the full scope of services. The commenter noted a potential correlation between restricted access to reproductive health care services and poor outcomes in other women's health areas, and recommended the State monitor related health outcomes and comparison of rates to those of MCOs without restrictions.

Response: Appendix B of the protocol (Attachment B of the final protocol) specifies documents for review and interview questions to address whether the MCO/PIHP has any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid service or services. This would include reproductive health services. For counseling and referral services the MCO/PIHP does not cover because of moral or religious objections, the Medicaid managed care final rule at § 438.10(f)(6)(xii) specifies that it is the State's responsibility to provide enrollees with information on where and how to obtain the service(s). The protocol is designed to address MCO/PIHP compliance with the BBA regulatory standards. Consequently, State monitoring of enrollee access to

the full scope of services and State monitoring of health outcomes in other women's health areas for enrollees with restricted access to reproductive health care services, and comparison of these rates to those of MCO/PIHPs without restrictions is beyond the scope of the protocol.

7. Emergency Services

Comment: One commenter suggested that the interview questions concerning inappropriate use of emergency rooms emphasize a comparison of their inappropriate use with access to routine and urgent care.

Response: We agree with the commenter and have therefore expanded the relevant interview questions in Appendix B of the protocol (Attachment B of the final protocol) under § 438.210 that addresses coverage and authorization of services to inquire about the potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care.

8. Delivery Network

Comment: One commenter recommended that the protocol, in reviewing the MCO's/PIHP's network of appropriate providers, consider specifically the providers needed to meet the needs of pregnant women, children and individuals with special needs, particularly those targeted for enrollment.

Response: In the Medicaid managed care final rule at § 438.206, we require the MCO/PIHP to establish a network of appropriate providers that considers the ''expected utilization of services, considering Medicaid enrollee characteristics and health care needs.'' We intend and expect that MCOs and PIHPs that serve pregnant women and individuals with special health care needs will consider their characteristics and needs. However, we do not explicitly identify them in this protocol because they are not explicitly mentioned in the regulation in this provision and because not all MCOs and PIHPs may serve pregnant women and individuals with special health care needs.

9. Access

Comment: One commenter suggested that the review address transportation services to network providers and out-of-network providers for enrollees without access within established time and distance standards, and for enrollees with disabilities and special needs.

Response: The regulations do not contain standards for the provision of transportation services to network or out-of-network providers, or for enrollees with disabilities and special needs. In addition, transportation is a service that may or may not be included under the MCO/PIHP contract. Therefore, in the protocol's document review and interview questions, we include only those transportation issues addressed in the regulation.

Comment: One commenter recommended that the monitoring of access to out-of-network providers include a review of the procedures for determining when in-plan access is unavailable and out-of-network services are appropriate; obtaining access to out-of-network services; and for providing in-plan services for enrollees denied out-of-network access.

Response: The protocol specifies a review of the MCO's/PIHP's administrative policies and procedures pertaining to the use of out-of-network providers. Although we reference documents by generic name or title, we explain that what is important is the presence or absence of evidence to determine compliance with the specified regulatory provision. We anticipate reviewers will use the relevant documents to determine compliance with all aspects of the regulatory provision regarding out-of-network access including those identified by the commenter.

Comment: One commenter suggested that the document review include policies, procedures, and criteria for determining that second opinions are rendered by qualified providers.

Response: We agree with the commenter. The protocol specifies a review of the MCO's/PIHP's administrative policies and procedures for providing enrollees with a second opinion from a qualified health care professional. As previously indicated, although the documents are referred to by generic name or title, we explain that what is important is the presence or absence of evidence to determine compliance with the regulatory provision. We anticipate reviewers will use the relevant documents to determine compliance with all aspects of the regulatory provision requiring that second opinions are rendered by qualified providers.

Comment: One commenter recommended that the document review related to direct access to women's health services be expanded to include materials produced by the State to inform MCOs and by MCOs to inform providers. The commenter suggested further that the review include policies and procedures for implementing direct access to these services.

Response: Within the review of enrollee rights, the protocol specifies a review of staff and provider orientation, education, and training curricula and materials, and other provider and staff communication tools for evidence that staff and providers consider, among the enrollees' rights, direct access to women's health services. We also specify the review of the results of MCO/PIHP monitoring of complaints and grievances, enrollee survey or other MCO/PIHP sources of enrollee information to detect violations of enrollee rights, including the provision of direct access to women's health services. However, we do not include in the protocol a review of materials produced by the State because the protocol is a review of MCOs or PIHPs, not State Medicaid agencies. Review of State compliance with Federal requirements is carried out by our regional office staff through a separate process.

Comment: One commenter recommended that the reviewer monitor the time it takes for enrollees to obtain appointments with network providers.

Response: We agree with the commenter. Our protocol directs the reviewers to obtain the State Medicaid agency's standards for timely access and to review documents showing how the MCO/PIHP ensures compliance and continuously monitors its network providers for compliance with the timely access standards. The protocol lists some acceptable mechanisms the MCO/PIHP may use for monitoring compliance.

Comment: One commenter suggested that inappropriate use of emergency rooms be evaluated according to the ''reasonable lay person'' standard. The commenter also recommended that the monitoring of emergency room use consider access to nonemergent care and follow-up outreach and education for enrollees using emergency rooms for nonemergency care.

Response: The protocol monitors MCO/PIHP application of the prudent layperson standard in the regulation at § 438.114. As we indicated in our response to a previous comment on emergency room use, we have added an interview question to inquire about the potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care. However, MCO/PIHP follow-up outreach and education for enrollees using emergency rooms for nonemergency care is not a regulatory requirement, and it would be inappropriate to include it in the protocol.

Comment: One commenter suggested expanding the protocol's activities to include the review of training curricula and materials on cultural and linguistic competency, including the scope and depth of the training, its frequency, and extent of staff attendance; the procedures for the translation and testing of enrollee informational materials; and arrangements with community-based organizations representing relevant ethnic groups.

Response: We disagree with the commenter. Our protocol addresses the extent to which an MCO/PIHP complies with the regulatory provisions that implement the Medicaid managed care sections of the BBA. The Medicaid managed care final rule, at § 438.206(c)(2), requires that MCOs/PIHPs participate in the State's efforts to promote the culturally competent delivery of services. Therefore, the protocol specifies a review of documents for evidence of the MCO's/PIHP's participation in the relevant State efforts. The inclusion of additional requirements not required by regulation within the protocol would be inappropriate.

10. Coordination & Continuity of Care

Comment: One commenter recommended that the review of coordination and continuity of care include interview questions regarding the provision of any specialty care services currently not provided in-network, and MCO efforts to make these services available in-network. The commenter also suggested that the interview questions be expanded to inquire what proportion of Medicaid enrollees with special health care needs have a person or entity formally designated as primarily responsible for coordinating their health care services.

Response: We agree, in part, with the commenter. Consequently, we have added an interview question for the organization leaders to inquire about the provision of any specialty care services currently not provided in-network. We have not added questions about MCO or PIHP efforts to make these services available in-network because it is not clear whether or not it is always necessary that all specialty services be provided by in-network providers. We have added additional potential interview questions for enrollee services staff to determine what proportion of Medicaid enrollees with special health care needs have a person or entity formally designated as primarily responsible for coordinating their health care services.

Comment: One commenter believes the protocol should differentiate between gatekeeping activities that are involved with utilization control and care coordination and case management functions that are related to supporting service access and coordination. The commenter believes further that reviewers should consider the MCOs' scope of responsibility for EPSDT case management, and how these services are provided or referrals are made.

Response: We agree with the commenter that a State may want to differentiate between care coordination models. In so doing, a State may decide to explicitly address care coordination for EPSDT care management. We specify in the protocol that MCOs/PIHPs may establish different coordination mechanisms, and in monitoring for compliance with the requirements for care coordination, direct the reviewers to obtain the State's requirements for MCO/PIHP care coordination programs.

Comment: One commenter recommended that the interview protocol address how and who conducts the MCOs' health screens; how the MCO assesses enrollee needs and determines if the provider is qualified to perform the assessment; how enrollees access case management services; how an enrollee's need for a treatment plan is determined; and how the providers are informed of the process. The commenter also suggested additional interview questions to address the number of treatment plans developed by categories of individuals, the number of denied requests for treatment plans and the reason for denial, and the number of treatment plans denied.

Response: The protocol includes interviewer questions for the case managers and care coordinators and for the enrollee services staff regarding the implementation of health screens, the conduct of health assessments for Medicaid enrollees, processes for care coordination, and procedures to determine how an enrollee's need for a treatment plan is determined. The protocol's interview questions for the provider/contractor services staff probe how providers are made aware of and are involved in procedures for assessments, treatment planning, and care coordination. We agree with the commenter regarding the need to explore the MCO's/PIHP's treatment planning. We have revised the protocol to include a series of questions for the case managers and care coordinators concerning the number of treatment plans developed, the number of denied requests for treatment plans and the reason for denial, and the number of treatment plans denied. However, our revision will not include a review of the treatment plans by categories of individuals. We do not require specific categories and, therefore, have no standard against which to measure the MCO's/PIHP's performance.

11. Prior Authorization

Comment: One commenter believes the protocol should include a review of prior authorization procedures and policies and a determination of their reasonableness, reflection of good medical practice, and timely application. The commenter suggested reviewers monitor the number of and reasons for delayed expedited requests, and the health consequences associated with prior authorization delays and denials of expedited authorizations. The commenter further believes the MCOs' informal communications with providers should be monitored, including the handling of provider telephone inquiries, resulting changes to the course of treatment, and provision of enrollee notice and appeal rights.

Response: We agree with the commenter regarding the need to determine compliance with the requirement for timely prior authorization decisions, and therefore have included in the protocol document review and interview questions to determine compliance. However, the regulations include no standards for the reasonableness of the policies and procedures or for their reflection of good medical practice; these issues are therefore beyond the scope of the protocol that is designed to assess compliance with the Medicaid managed care regulatory requirements.

We also agree with the commenter's suggestion to review the number and reasons for delayed expedited requests. We have revised the document review for service authorizations to include the review of tracking logs or other authorization record-keeping documents to address number and reasons for delayed expedited requests.

We do not agree with the suggestion to monitor health consequences associated with prior authorization delays and denials of expedited authorizations. We believe that determinations on whether health consequences were due to authorization delays or denials, or to the normal progression of the enrollees' health condition would be subjective. Further, States are required to maintain records of grievances and appeals and review this information as part of the State quality strategy. If enrollees' health outcomes are adversely affected by the MCO's/PIHP's handling of service authorization requests, this should become evident to the State through this grievance and appeals review.

Therefore, we have not added this review activity to the protocol. We are also not requiring the EQR to review informal communication with providers. Informal communications by their nature do not routinely involve written documentation, and we believe it would be burdensome to require reviewers to monitor verbal exchanges.

Comment: One commenter recommended that the interview questions address the MCO's process and criteria for extensions of the standard 14 days for regular prior authorization decisions.

Response: We disagree with the commenter: timeframes for standard prior authorization decisions are established by the State. The protocol addresses compliance with the standard requirements in the Medicaid managed care final rule. Because extensions to State-established timeframes for standard authorization decisions is not included in the regulations addressing enrollee services, it would be inappropriate to include it in the protocol.

12. Enrollment & Disenrollment

Comment: One commenter believes that the protocol should provide guidance to reviewers concerning when it is appropriate for enrollees to use the MCO's grievance process before the State makes a determination on the enrollee's disenrollment request.

Response: The Medicaid managed care regulation does not specify the circumstances under which it is appropriate for enrollees to use the MCO's/PIHP's grievance process before the State makes a determination on the enrollee's disenrollment request. The protocol is designed to address MCO/PIHP compliance with the regulatory provisions and is not intended as a vehicle for either specifying additional requirements or providing guidance.

Comment: One commenter recommended the protocol include comparisons of MCO disenrollment rates and default or automatic enrollment rates because high rates can signify quality or access problems in the former instance and information deficits in the latter.

Response: While we agree with the commenter that disenrollment rates and default or automatic enrollment rates may be correlated, we do not agree that a comparison of rates alone will suffice. Instead, we have revised the protocol to specify that the document review include the MCO/PIHP disenrollment rates, and that the review of the disenrollment sample determine if a relationship exists between the enrollees requesting disenrollment and enrollees enrolled in the MCO/PIHP automatically or by default.

13. Grievance System

Comment: One commenter suggested that the protocol include review of policies and interview questions to ensure the MCO does not deter enrollees from requesting fair hearings. The commenter recommended further that the reviewer consider the number of grievances and fair hearings versus the population served, and determine whether grievances are held in suspense at certain levels of the review process or enrollees are deterred from filing or pursuing grievance or fair hearing requests. The commenter also suggested the reviewer convene focus groups concerning how the grievance system is working.

Response: We believe the protocol, in the portion addressing review of documents related to enrollee grievances, appeals and State fair hearings, addresses the MCO/PIHP compliance with the regulatory provisions, and in so doing, ensures that the MCO/PIHP does not deter enrollees from requesting fair hearings or pursuing grievance or fair hearing requests. The protocol specifies a review of logs, registries, or other MCO/PIHP documentation of appeals, grievances, and requests for State fair hearings made by Medicaid enrollees. Further, States are required to maintain records of grievances and appeals and review this information as part of the State quality strategy. If grievances are held in suspense, this should become evident to the State through this grievance and appeals review. We believe that focus groups, like provider and consumer interviews, are time and resource intensive. Therefore, we include consideration of other accessory information, such as beneficiary surveys that may offer information on how the grievance system is working but do not require in this protocol that the reviewer convene focus groups.

Comment: One commenter believes that notice of action requirements (for denial, reduction or termination of services) apply to all types of plans and asked that this be clearly stated in the protocol. The commenter further suggested the protocol include interview questions to probe the actions that trigger notices required by due process of the law, and a review of the MCO's notices to determine that the notices comply with the legal requirements for adequate notice of hearing rights, assure enrollees the care they receive will not be affected because a grievance has been filed, are in languages prevalent in the service area, and clearly specify the action the MCO is taking.

Response: The protocol is designed to specifically determine MCO and PIHP compliance with provisions in the Medicaid managed care final rule, regardless of whether or not the provisions apply to other types of managed care plans. We have, therefore, addressed these two entities in assessing compliance with the requirements concerning notice of action. We believe a document review is more effective for this issue than interview questions as an approach to compliance determination. Furthermore, the protocol includes the review of a sample of MCO/PIHP notices to determine the extent to which notices include the legal requirements for adequate notice of hearing rights and specify the action the MCO/PIHP is taking. We agree with the commenter and have expanded this review to determine that notices include assurances that enrollees will not be treated differentially, and are in languages prevalent in the service area. We believe that by reviewing a sample of beneficiaries that have been denied services and the reasons for denials, reviewers will identify those actions that trigger notices required by due process of the law.

Comment: One commenter believes the protocol fails to ascertain the extent to which enrollees have realistic access to the grievance process. The commenter recommended that the protocol include interview questions concerning the process and frequency by which enrollees are informed of the grievance procedures. The commenter also suggested reviewers monitor the timeliness of grievance processing, interview enrollees regarding the free exercise of their rights, and review the MCO's procedures for supplying translation and interpretation services during the grievance process.

Response: As we noted in the prior response, we believe a document review is more effective than interview questions in determining compliance with these provisions. The protocol includes the review of the MCO/PIHP's administrative procedures and policies as well as a sample of MCO/PIHP notices. We agree with the commenter that reviewers should monitor the timeliness of grievance processing and review the MCO's/PIHP's procedures for supplying translation and interpretation services during the grievance process. Therefore, we have specified that in reviewing the sample of notices, the reviewer should determine the timeliness of grievance processing, and have included a review of the MCO's/PIHP's procedures for supplying

translation and interpretation services during the grievance process. However, since enrollee interviews are time and resource intensive and beneficiary survey results are specified for consideration as accessory information, we have not included this activity.

Comment: One commenter recommended reviewers interview enrollees to determine how they are informed of the right to request continuation of benefits pending resolution of an appeal or fair hearing, and whether continuing benefits were received when requested. The commenter also suggested that the reviewers compare the MCO's policies with the enrollees' experiences.

Response: As noted previously, enrollee interviews are time and resource intensive and are therefore not a review activity included in the protocol. Instead, reviewers are directed to review the results of beneficiary surveys as accessory information. The protocol also specifies a review of the MCO/PIHP administrative policies and procedures, and the review of a sample of notices, to determine the extent to which enrollees are informed of their right to request continuation of benefits pending resolution of an appeal or fair hearing. The findings from the document reviews can then be compared to the survey results as suggested by the commenter.

Comment: One commenter disagreed with the protocol not permitting the combination of case manager and care coordinator interviews with other interviews. The commenter further recommended the protocol include interview questions for case managers and care coordinators on the enrollees' process for accessing case management services to ensure consistency with MCO policies, the procedures for interfacing with carved-out or other services not covered by the MCO, and the ease of accessing specialist care.

Response: The protocol specifies that the case manager's and care coordinator's interviews may be combined with the Medical Director interview or the Utilization Management interview. This option is consistent with the process used by private accrediting bodies and in the Medicare program reviews. The protocol specifies potential interview questions for case managers and care coordinators to confirm MCO/PIHP compliance with the regulatory requirements pertaining to enrollee rights, service access, and coordination and continuity of care. However, if issues arise during the document review concerning the process for accessing case management services, for interfacing with carved-out or other services not covered by the MCO, or the ease of accessing specialist care, reviewers are directed to explore them during the interviews. We believe this direction affords the reviewers the flexibility necessary to appropriately tailor the review activity to the structure, operations, and circumstances identified for each MCO/PIHP. Further, we do not believe it is possible, given the diversity among States and MCOs/PIHPs and the scope of the review itself, to include in the list of potential interview questions probes to explore every possible problem or issue that might arise.

Comment: One commenter believes that in collecting accessory information it is important to consider non-Medicaid enrollee survey results and compare these to the Medicaid results to ensure all enrollees are receiving the same level of care.

Response: We believe there are numerous analyses of EQR-related activities that can be undertaken. Specifically, the results of compliance monitoring, encounter data, and performance measurements can all be compared, contrasted, analyzed, and correlated. We do not believe the Federal government can or should specify a single set of analyses that will yield the most useful information for all States and MCOs/PIHPs. We believe that States will choose their EQROs on the basis of their demonstrated competence in quality review and analysis, and we defer to the State's decisions about the lines of inquiry EQROs should pursue regarding all EQR-related data, including surveys of Medicaid enrollees and possible comparisons to Medicare enrollees, commercial enrollees, and SCHIP enrollees.

C. Protocols for Calculating or Validating Performance Measures

Comment: One commenter asked that clarification be provided regarding the collection and validation of performance measures. The commenter is concerned that there is no description of essential EQRO activities to ensure that the performance measures being used by the State are scientifically sound, meaningful, valid, and reproducible. The commenter does not believe that the collection methodology outlined in the protocols will ensure valid and reliable measures. The commenter recommended that we take steps to ensure that EQROs use only evidence-based performance measures.

Response: We disagree with the commenter. The protocols outline a methodology to be used in the validation or calculation of performance measures to ensure that valid and reliable measures are calculated or to determine the extent to which valid and reliable measures have been calculated by the MCO/PIHP. The protocols were designed to be consistent with approaches used by NCQA and Medicare QIOs but to also describe how to validate or calculate measures such as those found in HEDIS as well as those developed by States or other groups or organizations. We advocate the calculation of measures that have been tested and accepted in the private and public sectors but provide States with the flexibility to develop measures or use measures developed by others that meet their program needs.

In addition to specifying essential activities to be conducted as part of performance measure validation or calculation, we have provided an Appendix to this protocol that provides guidance on how to assess an MCO's or PIHP's underlying information system (IS) to ensure that valid and reliable data are used in the calculation of the performance measures. The IS assessment may be conducted as part of this protocol by the EQRO validating or calculating the performance measures, or the EQRO may review an assessment conducted by another party.

Comment: One commenter believes that States have already invested substantial resources in establishing systems to carry out performance measurement activities and that it is not clear how these established systems can be adapted easily to meet the requirements of the protocols.

Response: Because the essential components of the protocols are accepted practice in both the public and private sector, we expect that States will not have to significantly adapt their approaches to performance measurement. The performance measures protocols are to be used for validating measures calculated by the MCO or PIHP as required by the Medicaid managed care final rule or for calculating additional measures as directed by the State. State approaches to performance measurement might vary but we expect States to require the essential components of the protocol for performance measurement activities—review of MCO/PIHP data management processes, evaluation of compliance with specifications for performance measures, and verification of performance measurement.

Comment: One commenter believes this protocol is outdated and suggested we reference current industry tools. Another commenter argued that the performance measure validation process is heavily biased toward proprietary systems entities developed in the

business of accreditation. The commenter believes this bias limits flexibility in the process and promotes a narrow view of performance measurement and jeopardizes State's ability to be innovative in performance measurement.

Response: One reason we did not include the protocols in a regulation was because we recognize that the protocols will need to be updated as the state-of-the-art in quality assessment and improvement changes. However, we believe that the activities listed in the protocol are still those in current use in the industry. Further, to be in compliance with the EQR rule, States only need to ensure that our protocols or those consistent with ours are used.

In addition, we do not agree that the protocol is biased toward proprietary systems. We used three sources to develop the performance measures protocols (that is, NCQA's HEDIS validation protocol, IPRO documents, and documents from the MEDSTAT group). We identified activities common to these tools and incorporated those activities to ensure valid and reliable methods are used when calculating or validating performance measures. Only one of these tools was developed by an organization that is in the business of accreditation, and we do not agree that the performance measures protocol limits State flexibility in the performance measures development process. We provide States with the flexibility to use established measures or to develop their own measures. We recommend, however, when States choose to develop or use measures not widely used in the private and public sector, that these measures should be evidenced-based and tested.

Comment: Several commenters believe the process described for validating performance measures is bureaucratic and administratively burdensome. The commenters state that they do not understand the value of interviewing MCO staff and believe annual onsite review is not necessary and is burdensome.

Response: The process in the protocols for validating performance measures is consistent with the process used in the private sector and the Medicare program. We drew from established tools in the development of these protocols. The protocol includes interviewing MCO and PIHP staff in addition to reviewing MCO/PIHP documentation of how performance measures are produced. The purpose of interviewing staff is not to obtain information that can otherwise be obtained from documentation. It is to supplement and confirm information as needed. In the protocol, interviews of MCO/PIHP personnel are identified as an effective mechanism to understanding an MCO's/PIHP's IS and its application to performance measurement. While much information can be obtained by reviewing an MCOs/PIHPs internal documents describing its IS, we believe that interviews with MCO/PIHP staff can be a helpful adjunct to the review of IS documents in understanding the issues the MCO/PIHP has with respect to ISs and how it affects the MCO's/PIHP's production of performance measures.

Comment: One commenter argued that some States calculate and report MCO-level performance measures and therefore, much of what is contained in the calculating performance measures protocol is not applicable to MCOs, but is applicable to the State.

Response: We recognize that States may have MCOs and PIHPs submit encounter data to them instead of performance measures and, therefore, the State may be the entity calculating the performance measure. We have allowed for this in the quality assessment and performance improvement program requirements specified in § 438.240 of the Medicaid managed care final rule. However, regardless of who calculates the performance measures, MCO and PIHP-level performance measures must be calculated as required by the Medicaid managed care final rule and, if calculated by the MCO/PIHP, must be validated to provide information for the EQR function. We have added clarifying language under § 438.358(b)(2) to recognize that States may be calculating the MCO/PIHP performance measures and in this circumstance the State would provide the information obtained from this activity to the EQRO for the EQR function.

Comment: One commenter suggested combining the validating performance measures protocol and the calculating performance measures protocol to reduce the length and complexity of the two protocols.

Response: We purposefully provided separate protocols for each EQR-related activity. Even though some of the protocols are variations on a theme (for example, validating performance measures and calculating measures) we wanted to provide stand-alone documents for each activity. In addition, though the protocols are variations on a theme, the activities do differ somewhat and we believe the clearest way to present the information is in separate documents.

Comment: One commenter argued that the 30 sample medical record review recommended in the protocol for performance measures not calculated with administrative data only will add tremendous cost, is needlessly intrusive, and is very time consuming.

Response: This aspect of the protocol illustrates what we mean when we say that States must use protocols that are consistent with (but not identical to) our protocols. In this protocol, onsite Activity 4 is the ''Assessment of Processes to Produce Numerators.'' To be consistent with our protocol, the EQRO must perform this activity (that is, assess the MCOs' or PIHPs' processes to produce the performance measure numerator). In our description of Activity 4, we describe how this activity is to be conducted and state that this activity should include a review of a sample of the medical records used to determine the numerator. Thirty medical records is the number that was included in the private sector protocols we reviewed. However, EQROs may use another sample size and still be consistent with our protocol. Our protocol endorses the policies found in private sector protocols, that require a sufficient number of medical records be reviewed to validate a reported numerator for a given performance measure. As stated previously, however, activities used to provide information for the EQR must be conducted ''consistent with'' our protocols. ''Consistent with'' means that the protocols used contain all of the activities and steps included in our protocols. How EQROs and States implement the activities and steps is left to their discretion.

Comment: One commenter suggested we add lab data as a data source to calculating performance measures numerators (page 8, item 4).

Response: We agree with the commenter and have added laboratory data as a possible data source for calculating performance measures.

Comment: One commenter suggested some editorial changes.

Response: We have made editorial changes that were recommended where we thought appropriate and helpful.

Comment: One commenter suggested on page 15 we add ''place of service'' to the list of claims and encounter data elements to be assessed when assessing the integrity of the MCO's/PIHP's IS.

Response: We agree with the commenter and have added place of service to the list of claims and encounter data elements that may be used to conduct performance measurement.

D. Protocols for Conducting or Validating Performance Improvement Projects and Conducting Focused Studies

Comment: One commenter believes all the activities in this protocol are reasonable.

Response: We agree and retain the activities in the protocol.

Comment: One commenter asked for clarification of why the protocol for conducting performance improvement projects was developed. The commenter questioned the value of this protocol since the EQRO is not affiliated with any MCO and has no way to implement performance improvement initiatives affecting the actual delivery of care. The commenter recommended eliminating this protocol.

Response: This protocol was developed to provide EQROs and States guidance on the activities required when conducting performance projects as an optional EQR-related activity that qualifies for 75 percent FFP. A State may itself, through another State contractor, or through the EQRO, have additional performance improvement projects conducted other than those required to be conducted by the MCO/PIHP under § 438.240(b)(1) of the Medicaid managed care final rule and § 438.358(b)(1) of this rule. As long as the project is conducted consistent with the protocol, the information can be provided to the EQRO and be included as part of the EQR function. If the State itself or other State contractor conducts the activity, the State would not qualify for the 75 percent enhance match. If the EQRO conducts the performance improvement project, the State could claim the enhanced match. We developed separate protocols for the conduct of performance improvement projects and the validation of performance improvement projects to have stand-alone documents.

Comment: One commenter recommended that the focused study protocol be combined with the validating performance improvement projects protocol. The resulting protocol should be an optional protocol to be used at the State's discretion. One commenter recommended that the validating performance improvement projects and conducting performance improvement projects protocols be combined.

Response: We have developed separate protocols for validating and conducting performance improvement projects and for conducting a focused study of health care quality in order to provide stand-alone documents for each of the EQR-related activities. The focused study protocol and the conducting performance improvement projects protocol are to be used at the State's discretion if it decides to include information from these optional EQR-related activities as part of the EQR. In contrast, validating performance improvement projects conducted by MCOs/PIHPs is a mandatory activity. Although these protocols have much in common, there are some differences and we believe it is more helpful to the readers and users of the protocols to present these similar, but different activities in separate documents.

Comment: One commenter argued that the focused study protocol is biased towards proprietary measurement systems, that we advocate the use of indicators that are generally used in the public health community such as those developed by NCQA and the Foundation for Accountability (FACCT). The commenter recommended that the protocol be neutral in tone and approach the topic of performance measure selection from the perspective of State preferences and existing or evolving State-specified systems.

Response: We agree with the commenter that we advocate the use of performance indicators that are generally used in the public health and managed care industry. This is because these measures have been tested for validity and reliability and are widely accepted in the public and private sectors. However, we also, in the performance measures (both conducting and validating) and focused study protocols state that other indicators may be used. We recommend that these indicators be developed on the basis of current clinical practice guidelines or clinical literature derived from health services research or findings of expert or consensus panels.

Comment: One commenter suggested we add appointment availability studies, network assessment studies, open-closed panel reports, member and provider satisfaction survey data, and provider language reports as potential sources of information for selecting study topic for performance improvement projects or focused studies of health care quality.

Response: We agree with the commenter and have revised the potential sources of supporting information section, under Activity ''Selecting the Study Topic,'' in the performance improvement projects (conducting and validating) and focused studies protocols to include the following: data on appointments and provider networks such as access, open and closed panels, and provider language spoken. Data from surveys was already included in this section in each protocol.

Comment: One commenter suggested we add a discussion of service needs for special needs populations to the list of methods for selecting the study topic.

Response: We recommend in this section that topics should reflect high-volume or high-risk conditions of populations served, including populations with special health care needs such as children in foster care, adults with disabilities, and the homeless. We further state that although these populations may be small, their special health care needs place them at high risk. We believe these provisions address the commenter's concerns and that no change is needed.

Comment: One commenter believes that our rationale for reliable data collection only addresses clinical data collection. The commenter suggested we add a section for service studies such as appointment availability and that methods to implement this include review of appointment books, and ''secret shopper'' techniques when someone calls to make an appointment. These kinds of indicators require scripts and very clear definitions of items such as acute care, emergent care, and routine care.

Response: We agree with the commenter that we did not include a discussion on data collection issues when using nonclinical data. We have added a paragraph in the performance improvement projects (both conducting and validating) and focused studies protocols to address this issue.

E. Protocol for Validating Encounter Data

Comment: One commenter stated that the protocol does not allow for the fact that encounter data may be used for risk adjusted payment and/or other utilization data analysis purposes.

Response: Accurate and reliable encounter data is crucial to performing any analysis of utilization data, and in particular to the development of capitated payments which are based on utilization data. This protocol specifies processes for assessing the completeness and accuracy of the encounter data MCOs and PIHPs submit to the State. We believe this protocol for validation of encounter data accommodates the multiple purposes for which encounter data are used.

Comment: One commenter stated that this protocol is long, detailed, needlessly prescriptive and biased toward the MEDSTAT and HEDIS models. The commenter also stated that since States generally have encounter data validation processes in place, this

protocol will be redundant and should therefore be dropped, reformatted as technical assistance or combined with other protocols to reduce the length and complexity of the protocols.

Response: In developing this protocol (as with all the protocols) we instructed our contractor to draw from existing protocols that have been tested and used in the public and private sectors, and that are consistent with current industry practice. The elements contained in the MEDSTAT and HEDIS tools are consistent with other validation processes reviewed, and contain generic activities and steps that include the essential components of a methodologically sound review of encounter data. By requiring protocols that are ''consistent with,'' rather than ''identical,'' we believe that we have allowed for State flexibility while ensuring a minimum standard of quality. Since the validation of encounter data is an optional EQR-related activity, States have the option to conduct this activity or not. Consequently, we do not believe this protocol is redundant, needlessly prescriptive, or biased.

Comment: One commenter believes this protocol should address State data issues and improvements that may impede the ability of MCOs and PHPs to improve their data quality. These issues include the inability of the State to receive MCO and PHP data, unclear data specifications to MCOs and PHPs, and State policies and procedures.

Response: Section 4705(a)(2) of the BBA specifies that EQR be a review of MCOs. Therefore, these protocols focus on MCOs and PIHPs, not on the State. State Medicaid agencies have available to them a variety of approaches that use contractors to strengthen their Medicaid Management Information System (MMIS). Additionally, we have funding opportunities that assist States with improvements to their MMIS. We, therefore, are not modifying this protocol to address State Medicaid agency data issues.

Comment: One commenter asked for clarification about the purpose of the chart on page 11, including how the categories were decided upon, and who will calculate the elements.

Response: The ''Acceptable Error Rates Specifications and Identified Areas of Concern Form,'' is meant to serve as an example of a tool that an EQRO can use when assessing rates of accuracy and completeness for each data field. This tool can be used at the State's or EQRO's discretion. It may be adapted to meet individual State standards, or a State or EQRO may decide to develop a similar tool. Its purpose is to illustrate that States need to specify what error rate they will determine to be acceptable for the various types of encounter data to be submitted to them. The categories of ''encounter type'' were determined by the subcontractor that developed this protocol based on its extensive experience as a contractor to us and State Medicaid agencies on the production, assessment, and improvement of encounter data. The acceptable error rates should be specified by the State.

Comment: One commenter recommended against an analysis of mandatory fields (page 16) because these items are generally mandatory and an MCO's submission would not be accepted if any of the fields were not complete.

Response: We do not agree that an MCO's/PIHP's submission would not be accepted if any of the fields were not complete. State Medicaid agencies determine the acceptable levels of missing, surplus, or erroneous data. States also determine the standards for encounter data accuracy and completeness, to which encounter data submitted by MCOs and PIHPs will be compared. This protocol recommends that the encounter data validation process analyze and interpret the data in submitted fields to determine if the information is of the type that was requested by the State Medicaid agency, and if the values are valid and reasonable.

Comment: One commenter believes that because an MCO does not participate in or control the process of documenting the service in the medical record and subsequent billing that is based upon the medical record, there is no possibility for payor misbehavior.

Response: This protocol specifies processes for assessing the completeness and accuracy of encounter data MCOs/PIHPs submit. The protocol references reviews of medical records as an activity that is conducted to verify the accuracy of the automated data submitted, using the medical record as the point of reference. Payor misbehavior is not the issue. The issue addressed by this protocol is the accuracy of the information a provider submits, through the MCO/PIHP to the State, and the extent to which the MCO/PIHP has procedures in place to promote the accuracy and completeness of the data submitted by their providers.

Comment: One commenter believes the acceptable error rates form (page 5) is not information that can be assessed during an onsite visit.

Response: The Acceptable Error Rate form is a tool that can be used by the State or EQRO to document whether the MCO/PIHP has exceeded the acceptable error rate for each encounter type, and whether any concerns have been raised that trigger the need for further investigation. The protocol does not specify at what location (State Medicaid agency offices, MCO or PIHP offices, or EQRO offices) compliance with acceptable error rates is to be determined. The location where this form is to be constructed or used is to be determined by the State.

Comment: One commenter suggested that the protocol address rejected data.

Response: Activity 3, ''Analyze Electronic Encounter Data for Completeness and Accuracy,'' represents the core of the process the EQRO will use to test the validity of the encounter data. Activity 3 is designed to yield information about the general magnitude of missing encounter data, and should identify problems in the MCO's/PIHP's process for compiling and submitting encounter data. Rejected data should be included in the evidence of and reasons for an MCO's/PIHP's inability to submit encounter data. Additionally, Appendix Z (Information Systems Capabilities Assessment) asks what happens to the encounter if one or more required fields are missing, incomplete, or invalid.

Comment: One commenter suggested that the protocol address additional significant issues in performing data accuracy assessments. The commenter further recommended that it be clear before proceeding if the data are pre- or post-edits and whether they are from the MCO, the State, or from the State's data warehouse.

Response: We do not understand what the commenter is referring to when suggesting that the protocol address additional significant issues in performing accuracy assessments. In response to the second comment, the data that the protocol addresses is MCO/PIHP level data, and where the data resides is unique to each State. The protocol addresses encounter data submitted by the MCO/PIHP to the State. Therefore, the data would include any edits made by the MCO/PIHP. The State will need to identify to the EQRO the extent to which it has performed any edits of the data submitted by the MCO/PIHP.

Comment: One commenter suggested that the protocol address benchmark data that can be used to help determine data completeness.

Response: The use of benchmarks is discussed in a number of the Steps in Activities 2 and 3. The protocol does not specify exact benchmarks that are to be used because benchmarks should be

tailored to each State's status with respect to the accuracy and completeness of its encounter data. The protocol instead discusses how the EQRO should use benchmarks for testing the quality of data. Additionally, the protocol indicates the source for some benchmarks, and in some cases, provides instructions for EQROs to develop certain benchmarks.

Comment: One commenter suggested that the protocol address incorporation of vendor data in reporting to the State.

Response: We agree that vendor data should be included when reporting to the State. That is why we reference the importance of vendor data when assessing the MCO's/PIHP's capability to produce accurate and complete encounter data in Activity 2. Activity 2 directs the EQRO to conduct an IS assessment that is consistent with the process described in Appendix Z. Appendix Z includes as elements that impact the accuracy and completeness of encounter data, the MCO's/PIHP's data submission policies, and the contract requirements for vendors and contractors.

F. Information Systems Capabilities Assessment (Appendix Z)

Comment: One commenter believes the level of detail required in the information systems capabilities assessment (ISCA) tool is excessive. The commenter does not believe that the reviewer should have the option of asking for the source code for a variety of computer and report programs. Moreover, the commenter stated that MCOs do not necessarily have the source code because that information may be proprietary and may be the property of a vendor.

Response: We do not agree that the ISCA tool requires an excessive level of detail. A number of public and private sector protocols and tools were examined to promote consistency between this assessment and similar public and private sector activities. We also disagree with the comment that the reviewer does not need the source codes used to perform various calculations, and because these codes are proprietary the MCO/PIHP would not have access to this documentation. The source codes referred to in the protocol are codes used in the programs written by MCO/PIHP staff or by their contractors to calculate continuous enrollment or other calculations using MCO/PIHP administrative data. Consequently, whenever the accuracy of calculations performed by the MCO/PIHP impact on other aspects of the quality measurement; for example, performance measures, the EQRO will require source codes to validate the accuracy of those calculations. These source codes should, therefore, be available to the MCO/PIHP.

Comment: One commenter believes the onsite activities under this Appendix probe policies and procedures not subject to regulation and that they are not relevant to the State MCO contract.

Response: We disagree with the premise that the policies and procedures related to the MCO/PHP ISCA are not subject to regulation. This Appendix relates to three different regulatory provisions. Under § 438.242 of the Medicaid managed care final rule, the State must ensure, through its contracts, that each MCO/PIHP maintains an IS that accurately and completely collects, analyzes, integrates, and reports data on utilization, enrollment and disenrollment. Additionally, § 438.240 stipulates that the State must require MCOs/PIHPs to have an ongoing quality assessment and improvement program for which accurate and complete data is an essential element. Further, in § 438.350 of this final rule, each State is required to provide its EQRO information obtained through methods consistent with these protocols. In our contractor's review of private sector industry and Medicare practices, it was determined that an assessment of an MCO's/PIHP's IS is an essential component of validation of encounter data and performance measurement.

Comment: One commenter believes that this Appendix is outdated and suggested the encounter data protocol should reference current industry available tools.

Response: When we started developing the protocols we used the most recent version of the public and private sector tools referenced. These private and public sector tools have since been updated. However, because we developed the protocols as generic activities and steps to be used in the conduct of the EQR-related activities, we do not agree that the protocols are outdated. Furthermore, in this final rule we allow for use of other protocols, as long as they are consistent (that is, contain the activities and steps identified in these protocols) with those we have developed.

Comment: One commenter believes that States may routinely assess MCO IS capabilities and in these cases this protocol is of limited applicability.

Response: To avoid duplication, in all the protocols calling for an ISCA, we state that the EQRO may use information about the MCO/PIHP ISCA obtained from an ISCA conducted by another party as part of another review such as the validation of performance measures, validation of encounter data, or a review for compliance with standards. If the ISCA was performed by another party as part of another review, the State or EQRO should obtain a copy of the assessment, review it to determine if the findings are current, consistent with this Appendix, and where appropriate, seek more recent or additional information. If a recent assessment has not been conducted, an ISCA that is consistent with this Appendix should be conducted.

G. Protocols for Administering or Validating Surveys

Comment: One commenter argued that the protocol for administering a survey is very prescriptive and the value of such a detailed protocol is questionable particularly when States choose to follow the recommended CAHPS survey method. The commenter asked us to clarify how much latitude there was to follow the CAHPS methodology.

Response: The administration of validation of consumer or provider surveys of quality of care are optional EQR-related activities. If a State elects to have its EQR perform these activities and to qualify for the 75 percent enhanced match, our protocol or a protocol consistent with ours must be used. Our protocol includes generally accepted practices of survey design and implementation. We relied upon, but condensed, generally accepted principles of survey design and administration discussed in textbooks and other health services publications. Although many States use CAHPS surveys (and the CAHPS survey methodology would meet the requirements of this protocol) it was necessary to put forth this protocol to cover those instances when States desired to use a survey other than a CAHPS survey.

Comment: One commenter asked us to clarify the distinctions between the two survey protocols.

Response: The first protocol applies to the situation in which the State or its agent administers a survey, that is, designs and/or conducts a survey. Administration of a survey may include the design and implementation of a new survey or the modification of an existing survey and its implementation.

The second protocol applies to the situation in which the State or its agent validates the use of a survey administered or conducted by another party. The process of validation is necessary to ensure that the survey results are both reliable and valid. In

this protocol, survey validation is limited to a review of the survey procedures. The validation process does not include collecting survey data anew from respondents to verify their responses.

Comment: One commenter believes that beta testing all surveys and the additional questions to members and providers would be time consuming and cost prohibitive.

Response: The protocols do not suggest beta testing of all surveys. Instead, they acknowledge the commitment of time and resources and the demands on survey respondents that make such an activity infeasible. The protocol suggests that survey validation be limited to a review of survey procedures.

H. Other Appendices (Attachments to Final Protocols)

Comment: One commenter recommended that we explain the obligations of the State or the EQRO with regard to the documents included in the appendices (for example, what is the role of the documents and how the documents are to be used).

Response: With the exception of Appendix Z, ISCA for MCOs and PIHPs, the appendices (Attachments to the final protocols) provide additional guidance to States and EQROs on how to implement the EQR-related activities. The information contained in the appendices (Attachments to the final protocols) are to be used at the discretion of the State or EQRO based on the particular circumstances of the activity being conducted and other means of obtaining needed information.

I. Section 438.360 (Nonduplication of Mandatory Activities)

Comment: One commenter believes the estimates of the time necessary to collect the information under this provision are too low. In addition, the commenter believes that this function needs to be performed by both professional staff and clerical staff and that a blend of the hourly costs should be used to determine the estimated costs.

Response: As we stated earlier, because we received several comments indicating that this estimate is low but commenters did not provide us with what they believe the correct estimate to be, we have increased the burden hours by 100 percent to 8 hours. We have taken the commenters recommendation and blended the hourly costs to reflect that both professional and clerical staff will partake in this effort.

J. Section 438.362 (Exemption From EQR)

No comments were received on this section.

K. Section 438.364 (EQR Results)

No comments were received on this section.

IV. Provisions of the Final Regulation

For the most part, this final rule adopts the provisions of the December 1, 1999 proposed rule. In response to public comments, we have made clarifying wording changes. Those provisions of this final rule that differ from the provisions of the December 1, 1999 proposed rule follow.

Section 438.310—Basis, Scope, and Applicability

We have revised this section to reference the applicability of this rule to PIHPs. We have added the reference to PIHPs throughout the rule as appropriate.

Section 438.320—Definitions

We have revised this section by adding clarifying language to the definitions for the terms ''EQR'' and ''EQRO'' and adding a definition for the term ''financial relationship.'' The definition of EQR has been revised to clarify that this rule applies to the care provided to Medicaid beneficiaries that receive health care services furnished by MCO and PIHP subcontractors as well as MCOs and PIHPs. This definition has also been revised to clarify that EQR-related activities are not considered part of the EQR function. We have revised the definition of EQRO to mean an organization that conducts the EQR function as well as EQR-related activities. EQR-related activities had not previously been included in the EQRO definition. As a result of this clarifying language, how we use the terms EQR, EQR-related activities, and EQRO needed to be changed in several sections of this rule.

Section 438.350—State Responsibilities

We have revised this section to add clarifying language that the information provided to the EQRO is consistent with the information we require as part the EQR results; for each EQR-related activity that provides information for the EQR, the EQRO must have the objectives of the activity, the methods of data collection and analysis, a description of the data obtained, and the conclusions drawn.

Section 438.352—External Quality Review Protocols

We have revised this section to add clarifying language at paragraph (c) of this section to explain what we meant by each protocol must specify the ''detailed procedures'' to be followed in collecting the data to promote its accuracy, validity, and reliability. We have changed the wording of ''detailed procedures'' to ''activities and steps'' to be consistent with how the EQR protocols have been designed.

Section 438.354—Qualifications of External Quality Review Organizations

We have revised this section to add at paragraph (b)(1) that the EQRO must have ''demonstrated experience'' as well as knowledge of the Medicaid recipients, policies, data systems, and processes; managed care delivery systems, organizations, and financing; quality assessment and improvement methods, and research design and methodology.

We have revised paragraph (c) of this section to require that all EQROs, as opposed to only State entities that qualify as EQROs, may not deliver any health care services to Medicaid beneficiaries, or conduct on the State's behalf ongoing Medicaid managed care program operations related to the oversight of MCO or PIHP quality of services. This later provision has been revised to apply only to Medicaid managed care operations as opposed to all Medicaid program operations. This provides States the opportunity to contract with a broader group of entities than was provided for in the December 1, 1999 proposed rule.

We have also revised paragraph (c) of this section to add clarifying language to explain how ''control'' is defined in 48 CFR 19.101. In addition, we have added a provision that prohibits an entity from qualifying as an EQRO if it has a financial relationship with an MCO or PIHP that it will review as an EQRO.

Section 438.356—State Contract Options

We have revised paragraph (a) of this section to clarify that States may only contract with one entity for EQR alone or EQR and other EQR-related activities, but may contract with multiple entities to conduct additional EQR-related activities.

Section 438.358—Activities Related to External Review

We have revised this section by adding cross-references to the Medicaid managed care final rule. We have made these cross-references throughout this rule where appropriate. We had not

included these cross-references in the December 1, 1999 proposed rule as the Medicaid managed care final rule had not yet been published.

We have added a general rule under paragraph (a) to clarify that the mandatory and optional EQR related activities can be conducted by the State, the State's agent that is not an MCO or PIHP, or an EQRO.

We have revised paragraph (b)(1) to clarify that information from the validation of performance improvement projects that are underway, as opposed to those being performed, must be obtained from the MCO or PIHP. We have revised paragraph (b)(2) to clarify that information on performance measures can be obtained from either those calculated by the MCO/PIHP and validated by the State or its agent, or those calculated by the State on behalf of the MCO/PIHP. We have also revised (b)(3) by eliminating the reference to specific State standards. These are now referenced in the aggregate by our cross-reference to the Medicaid managed care final rule provision. We have also revised paragraph (c) to clarify that information from optional activities must be from information derived within the preceding 12 months.

Section 438.360—Nonduplication of Mandatory Activities

We have revised this section by removing the word ''exempt.'' Using this word caused confusion with the ''exemption of EQR requirements'' under § 438.362. In its place, we provide language that explains that the nonduplication provisions allow States to use information from either a Medicare or accreditation review for certain standards and activities in place of a Medicaid review.

We have also revised this section to allow States to apply this provision to MCOs and PIHPs that provide health care services to commercial consumers of health care as well as Medicare beneficiaries. We have further revised this section to clarify that national accrediting organizations are those organizations that have been approved and recognized for M+C deeming. We have made this clarification throughout the rule as appropriate.

We have restructured this section by revising paragraph (b) so it applies to both M+C and MCOs and PIHPs that provide services to commercial consumers and have revised paragraph (c) to address additional provisions for those MCOs and PIHPs providing services to dually eligible beneficiaries only. Under paragraph (b) and (c), we have added a provision that requires the State in its quality strategy to identify those standards and activities for which it will substitute the Medicare or accreditation review for the Medicaid review. In addition, we require the State to explain the rationale for why the State considers the standards or activities duplicative.

Section 438.362—Exemption From External Quality Review

We have revised paragraph (a)(2) to clarify that the Medicare and Medicaid contract must overlap geographically within the State when it exempts the MCO or PIHP from EQR. The December 1, 1999 proposed rule did not require that the overlap be within the State.

We have revised (b)(1) to clarify that information from Medicare reviews is to be obtained by the State from the MCO or PIHP. The language in the December 1, 1999 proposed rule could have been misinterpreted to mean that the State had to obtain the information from CMS or its agent. We have also revised paragraph (b)(2) to clarify that the MCO or PIHP must provide the State a copy of the accreditation review findings as opposed to ensuring the State receives a copy.

Section 438.364—External Quality Review Results

We have revised paragraph (a)(1) to clarify that in the detailed report, conclusions are drawn as to the timeliness of and access to care as well as the quality of care. We have revised paragraph (a)(1)(iii) to clarify that the detailed report should include a ''description'' of the data obtained for each EQR-related activity as opposed to the data obtained. We did not intend for the raw data to be provided as part of the EQR results. We have also revised paragraph (a)(2) to require an assessment of the MCO's and PIHP's strengths and weaknesses be addressed as opposed to a ''detailed'' assessment of the MCO's and PIHP's strengths and weaknesses.

We have revised paragraph (b) to require that the EQR results, upon request, be made available in alternative formats for persons with sensory impairments and that the EQR results be made available through electronic as well as printed copies.

Section 438.370—Federal Financial Participation

We have revised (a) to clarify that 75 percent FFP is also available for the production of the EQR results.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for §§ 438.352, 438.360, 438.362 and 438.364 of this document that contain information collection requirements.

We published a notice in the **Federal Register** on November 23, 2001, to give the public a 60-day period in which to comment. The basic purpose was to afford the public an opportunity to comment on the protocols. We have addressed the comments received in response to this **Federal Register** notice in section III. above.

For purposes of this requirement, we incorporated Medicaid managed care data from the 2001 Medicaid enrollment report. As of June 2001, there were 329 MCOs (this includes 5 HIOs that must adhere to the EQR requirements of this regulation), and 129 mental health and substance abuse PIHPs.

§ 438.358 (Activities related to EQR)—For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were under way during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures, respectively)

established by the State to comply with the requirements of § 438.204(g).

In addition, if a State, at its option, wishes to provide additional information to its EQRO, and to have CMS provide 75 percent FFP in the costs of producing this information, then the additional information must be produced through activities identified as optional activities in this final rule and also must be produced in a manner consistent with (as opposed to identical to) the protocols for these six optional activities. These six optional activities are (1) validation of client level data such as claims and encounters, (2) administration or validation of a survey, (3) calculation of performance measures, (4) conduct of performance improvement projects, and (5) conduct of focused studies of quality of care.

The burden associated with this requirement is the time and effort for a State, EQRO, or other State contractor, to conduct and document the findings of the three mandatory activities—the validation of performance improvement projects conducted by the MCO/PIHP, the validation of performance measures calculated by the MCO/PIHP, and a review of MCO/PIHP compliance with structural and operational standards. Each of these activities will need to be conducted on the 329 MCOs and 129 PIHPs that we estimate are currently providing Medicaid services. The types of services provided by these managed care entities and the number of performance improvement projects conducted and performance measures calculated will vary.

We interviewed four EQROs who in 2000 reviewed MCOs/PIHPs in 16 mandatory or voluntary managed care programs in eight States. Based on the information provided by the four EQROs, we confirmed that the hours and costs to conduct these activities vary. The information provided includes: (1) It takes 25 to 138 hours at a cost of $2,000 to $10,000 to validate a performance improvement project conducted by an MCO/PIHP; (2) it takes 12 to 202 hours at a cost of $1,200 to $7,000 to validate a performance measure calculated by an MCO/PIHP; and it takes 200 to 800 hours at a cost of $11,000 to $49,000 to review for MCO/PIHP compliance with structural and operational standards. Based on the submitted information, it takes an average of 65, 53, and 361 hours, respectively, to conduct the above mandatory EQR activities. Therefore, the average total burden associated with this requirement is 479 hours x 458 entities (329 MCOs + 129 PIHPs). Assuming wages of $63 per hour for professionals to comply with the requirement, the cost is $13,821,066.

For the optional EQR activities—validation of client level data (such as claims and encounters), administration or validation of consumer or provider surveys, calculation of performance measures, conduct of performance improvement projects, and conduct of focused studies—we have no data to estimate the hours associated with how long it will take to conduct these activities. We, therefore, estimate that it will take 350 hours to validate client level data and 50 hours to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures as it takes on average to validate (159 hours) and three times as long to conduct performance improvement projects and focused studies as it takes on average to validate performance improvement projects (195 hours). We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (150 hours).

Based on 2001 State reported data, we know that of the 42 States that had capitated programs (MCOs or PIHPs) in 2001, 29 (69 percent) had their EQROs validate MCO/PIHP encounter data, 18 (43 percent) had their EQRO administer or validate consumer or provider surveys, 12 (29 percent) had their EQRO calculate performance measures, 16 (38 percent) had their EQRO conduct performance improvement projects, and 32 (76 percent) had their EQRO conduct focused studies. Using the aforementioned percentages and applying them to the number of MCOs and PIHPs, we estimate that States will contract with their EQROs to validate the encounter data of 316 MCOs/PIHPs, administer or validate consumer or provider surveys of 197 MCOs/PIHPs, calculate performance measures of 133 MCOs/PIHPs, conduct performance improvement projects of 174 MCOs/PIHPs, and conduct focused studies of 348 MCOs/PIHPs.

We, therefore, estimate the average total burden associated with conducting each optional EQR activity as follows:

- Validating client level data 350 hours × 316 MCOs/PIHPs = 110,600 hours.
- Validating consumer or provider surveys 50 hours × 98 MCOs/PIHPs (½ of 197 MCO/PIHPs that administered or validated surveys) = 4,900 hours.
- Administering consumer or provider surveys 150 hours x 99 MCOs/PIHPs (½ of 197 MCO/PIHPs that administered or validated surveys) = 14,850 hours.
- Calculating performance measures 159 hours × 133 MCOs/PIHPs = 21,147 hours.
- Conducting performance improvement projects 195 hours × 174 MCOs/PIHPs = 33,930 hours.
- Conducting focused studies 159 hours × 348 = 55,332 hours.

Assuming a wage of $63 per hour for professionals to comply with the requirement, the cost of conducting the optional EQR activities is (240,759 hours × $63) $15,167,817. We solicit comments specifically on this issue because we had no data on which to base the estimated hours for the conduct of each of the optional EQR activities.

The burden estimate associated with this requirement also includes the time and effort for an MCO/PIHP to prepare the information necessary for the EQRO or other State contractor to conduct the three mandatory activities—the validation of performance improvement projects conducted by the MCO/PIHP, the validation of performance measures calculated by the MCO/PIHP, and a review of MCO/PIHP compliance with structural and operational standards. We estimate that it will take each MCO and PIHP 160 hours to prepare this documentation. We believe one-half of the time preparing the information will be done by professional staff at $63 per hour and the other one-half of the time preparing the information will be done using clerical staff at $12 per hour. Therefore, to comply with the requirement, the cost of compiling the necessary information is (458 MCOs/PIHPs × (80 hours × $63 + 80 hours × $12) $2,748,000.

§ 438.360 (Nonduplication of mandatory activities)—In order to avoid duplication, the State agency may allow the MCO/PIHP to substitute information from a Medicare or accreditation review for the Medicaid review if specified conditions are met. To demonstrate compliance with these requirements an MCO/PIHP must provide to the State agency reports, findings, and other results of the Medicare or private accreditation review. The burden associated with these requirements is the time and effort for an MCO/PIHP to disclose the reports, findings, and other results of the Medicare or private accreditation review to the State agency. Of the 329 MCOs and 129 PIHPs providing Medicaid services, approximately 122 are Medicaid-only MCOs. We believe that there is the potential for States to allow the remaining 336 MCOs/PIHPs to take advantage of the nonduplication provision and that these MCOs/PIHPs will be required to disclose the necessary information to each State

agency. We estimate that it will take each MCO 8 hours to disclose the necessary documentation to the State, 4 hours of professional time and 4 hours of clerical time. Therefore, the total burden associated with this requirement is 336 MCOs/PIHPs × 8 hours = 2688 annual burden hours. At $37.50 per hour ($12 + $63/2), the cost will be $100,800.

This section also requires that a State agency provide the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO. We estimate that it will take, on average, 8 hours for a State to disclose the necessary documentation to the appropriate EQRO. The total annual burden associated with this requirement is 2688 hours ($37.50 per hour) and $100,800.

This section also requires a State to include in its quality strategy information concerning the activities or standards for which it is obtaining information from Medicare or an accrediting organization. We believe that the burden for this information collection requirement is included in the burden addressed in the Medicaid managed care rule and approved under OMB number 0938.

§ 438.362 (Exemption from EQR)—Each year, exempted MCOs/PIHPs must provide to the State agency the most recent Medicare review findings reported to the MCO/PIHP. This information must include (1) all data, correspondence, information, and findings pertaining to the MCO's/PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities; (2) all measures of the MCO's/PIHP's performance; and (3) the findings and results of all performance improvement projects pertaining to Medicare enrollees.

If an exempted MCO/PIHP has been reviewed by a private accrediting organization and the survey results have been used to either fulfill certain requirements for Medicare external review under 42 CFR part 422, subpart D or to deem compliance with Medicare requirements as provided in § 422.156, the MCO/PIHP must submit a copy of all findings pertaining to its most recent accreditation review to the State agency. These findings must include accreditation survey results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

The burden associated with these requirements is not applicable for 2 years following the final publication of this regulation. After 2 years, the time and effort for an exempted MCO/PIHP to disclose the findings of its most recent Medicare or private accreditation review to the State agency will be the burden associated with these requirements. We estimate, of the approximately 202 MCOs that potentially may provide Medicare services in addition to Medicaid services, State agencies will allow for approximately 10 percent of the MCOs to be exempt from the EQR requirement. We further estimate that it will take each MCO 8 hours to prepare and submit the necessary documentation to the State agency. Therefore, the total burden associated with this requirement is 10 percent of 202 MCOs × 8 hours = 160 annual burden hours. At a cost of $37.50 ($12 + $63/2) per hour, we assume a total cost of $6,000.

§ 438.364 (EQR results)—The EQRO responsible for the EQR function will be required to provide to the State agency a detailed technical report that describes for each mandatory and optional activity undertaken for the EQR, the objectives, technical methods of data collection and analysis, a description of the data obtained, conclusions drawn from the data, and the manner in which the conclusions were drawn as to the quality of the care furnished by the MCO/PIHP. In addition, the report must include: (1) An assessment of each MCO's/PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries; (2) recommendations for improving the quality of health care services furnished by each MCO/PIHP; (3) as the State agency determines methodologically appropriate, comparative information about all MCOs/PIHPs, and (4) an assessment of the degree to which each MCO/PIHP has addressed effectively the recommendations for quality improvement, as made by the EQRO during the previous year's EQR.

The burden associated with this requirement is the time and effort for an EQRO to submit to a State agency a detailed technical report for each EQR conducted. We estimate that it will take an EQRO 200 hours to prepare and submit the necessary documentation to the State agency. Therefore, the total burden associated with this requirement is 458 technical reports (329 MCOs + 129 PIHPs) × 200 hours = 91,600 annual burden hours. Assuming wages of $63 per hour for professionals to comply with this requirement, the cost is $5,770,800.

This section also requires each State agency to provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP, beneficiary advocate groups, and members of the general public.

The burden associated with this requirement is the time and effort for a State agency to disclose copies of a given technical report to interested parties. We estimate that on average, it will take a State agency 8 hours to disclose the required information. Therefore, the total burden associated with this requirement is 329 MCOs + 129 PIHPs × 25 requests per MCO or PIHP × 8 hours = 91,600 annual burden hours and a cost ($12 per hour) of $1,099,200.

The information collection requirements contained in this final rule will be submitted to OMB for review. In accordance with the Paperwork Reduction Act, these requirements will not go into effect until approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail 3 copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; Attn: Julie Brown, HCFA–2015–F; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. 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 effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually. Individuals and States are not included in the definition of a small entity.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that 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 604 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 a Metropolitan Statistical Area and has fewer than 100 beds.

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $110 million or more. This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $110 million or more.

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this regulation will not significantly affect States rights, roles, and responsibilities. Section 1903(a)(30)(C) of the Act currently requires an EQR for each contract a State has with a section 1903(m) organization. In accordance with section 4705 of the BBA, this rule will establish requirements and procedures for EQR of Medicaid MCOs. We require States to ensure that an annual EQR is performed by a qualified EQRO for each contracting MCO, the EQRO has adequate information to carry out the review, and that the results of the reviews are made available to interested parties such as participating health care providers, enrollees, advocate groups, and the general public. We also require that these EQR provisions apply to PIHPs and certain entities with comprehensive risk contracts that have been exempted from the requirements of section 1903(m) of the Act. We believe this is consistent with the intent of the Congress in enacting the quality provisions of the BBA. This rule would not require State agencies to dismantle EQR mechanisms that they have used to meet section 1902 (a)(30)(C) of the Act and which they have found to be effective and efficient. Rather, this rule would provide States greater flexibility in the types of entities they may use to conduct EQR.

We worked closely with States in developing this regulation. Specifically, in accordance with section 1932(c)(2)(A)(ii) of the Act, which requires the Secretary to consult with States to establish a method for identifying entities qualified to conduct EQR, we met with States and other stakeholders under the auspices of the NASHP to establish a criteria to identify qualified entities. Most of the recommendations made at this meeting have been incorporated into this rule. For recommendations not accepted, an explanation was provided in the December 1, 1999 proposed rule.

In addition, section 1932(c)(2)(A)(iii) of the Act requires the Secretary to coordinate with the NGA in contracting with an independent quality review organization to develop protocols to be used in EQR. To meet this requirement, we issued a request for proposal for one or more contractors to develop a set of review protocols for EQROs to use in the conduct of EQRs. Two State representatives selected by the NGA were members of the panel that reviewed and rated responding proposals. Moreover, part of the development of the EQR protocols includes convening an expert panel for review and comment of the protocols. State representatives were included in this process.

B. Anticipated Effects

In publishing this final rule, we considered two main alternatives. The first was to allow this final rule to be published, incorporating public comments on the proposed rule. The second alternative was to implement the provisions of the BBA as written, without expanding the regulations beyond the statutory language. We believe this final rule as written was the appropriate alternative to choose. Used in conjunction with the Medicaid Managed Care final rule published June 14, 2002, this final rule is a necessary tool for States to use to create and maintain strong, viable Medicaid managed care programs that deliver high quality health care in their State marketplaces and health care delivery systems. Further, we felt this final rule was necessary to implement the Congress' directive to the Secretary to establish a method for identifying entities qualified to conduct EQR.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on State agencies and MCOs, but not directly on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this final rule will not have a significant impact on the operations of a substantial number of hospitals. The only other small entity affected by these regulations would be the EQROs. However, this rule does not impose additional burdens on them. Instead, the rule offers these organizations the benefit of opportunities for additional revenues. Thus we certify that this rule will not have a significant economic impact on a substantial number of small entities.

We do not anticipate a significant increase in Medicaid expenditures as a result of the publication of these regulations for the following reasons. First, approximately 42 States are currently obtaining 75 percent enhanced FFP for EQR activities carried out by QIOs and organizations that meet the requirements to contract with Medicare as a QIO. Permitting these State agencies to claim 75 percent matching for EQR activities conducted by the additional types of entities allowed by these regulations would therefore not result in increased costs to the extent that State agencies switch from QIO or organizations that meet the requirements to contract with Medicare as a QIO to these other entities. Moreover, we believe that, by expanding the pool of organizations available to conduct EQR, State agencies may be able to negotiate savings compared to current costs of dealing with PRO and PRO-like organizations. Additional savings may be realized through opportunities afforded by the final rule to coordinate EQR activities with quality reviews conducted for other purposes. Additional costs may arise where State agencies currently conduct quality review activities at 50 percent Federal matching rate that would now qualify for 75 percent, and from new EQR activities undertaken as a result of the BBA requirements.

In addition, even though we extend this requirement to PIHPs, again we do

not expect this to significantly increase Medicaid expenditures. PIHP costs account for approximately 5 percent of the payments we make to capitated arrangements. Furthermore, State agencies currently conduct quality review activities on PIHPs at a 50 percent Federal matching rate. Additional costs may arise for States' quality review activities that would now qualify for 75 percent and for new quality review activities undertaken as a result of the activities required in this rule.

Although we cannot quantify these various cost and savings effects, we believe that their net impact would be well below the $100 million threshold for a major rule, and therefore that a regulatory impact analysis is not required. We do not believe that this final rule will cause MCOs to devote significantly more time to collect, organize and prepare for EQR than is already required by States. While the scope of work for EQR may be different under this final rule, we do not believe that the cost difference will be significant and States may actually be able to achieve savings since we are expanding the pool of organizations available to conduct EQR. Further, additional savings may also be realized through opportunities afforded by this rule to coordinate EQR activities with other quality and oversight activities. We acknowledge with the increased opportunity to contract with other qualified entities to conduct EQR, more States may avail themselves the 75 percent match for EQR activities. However, we do not believe this would represent a significant cost impact.

C. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and record keeping requirements.

42 CFR Part 438

Grant Programs—health, Managed care entities, Medicaid, Quality assurance, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below.

PART 433—STATE FISCAL ADMINISTRATION

A. Amend part 433 as set forth below.

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

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 433.15, add a new paragraph (b)(10) to read as follows:

§ 433.15 Rates of FFP for administration.

* * * * *

(b) * * *

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter when they are performed by an external quality review organization as defined in § 438.320 of this chapter: 75 percent.

B. Add a new subpart E to part 438 to read as set forth below.

PART 438—MANAGED CARE

Subpart E—External Quality Review

Sec.

438.310 Basis, scope, and applicability.
438.320 Definitions.
438.350 State responsibilities.
438.352 External quality review protocols.
438.354 Qualifications of external quality review organizations.
438.356 State contract options.
438.358 Activities related to external quality review.
438.360 Nonduplication of mandatory activities.
438.362 Exemption from external quality review.
438.364 External quality review results.
438.370 Federal financial participation.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart E—External Quality Review

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(2), 1903(a)(3)(C)(ii), and 1902(a)(4) of the Act.

(b) *Scope.* This subpart sets forth requirements for annual external quality reviews of each contracting managed care organization (MCO) and prepaid inpatient health plan (PIHP), including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews; and

(4) Standards for making available the results of the reviews.

(c) *Applicability.* The provisions of this subpart apply to MCOs, PIHPs, and to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act.

§ 438.320 Definitions.

As used in this subpart—

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO or PIHP, or their contractors furnish to Medicaid recipients.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.350 State responsibilities.

Each State that contracts with MCOs or PIHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO or PIHP;

(b) The EQRO has sufficient information to use in performing the review;

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358.

(d) For each EQR-related activity, the information must include the elements described in § 438.364(a)(1)(i) through (a)(1)(iv);

(e) The information provided to the EQRO in accordance with paragraph (c) of this section is obtained through methods consistent with the protocols established under § 438.352; and

(f) The results of the reviews are made available as specified in § 438.364.

§ 438.352 External quality review protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs or PIHPs that they review. To qualify as ''independent''—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO or PIHP if either the EQRO or the MCO or PIHP exerts control over the other (as used in this paragraph, ''control'' has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid recipients;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO or PIHP services, except for the related activities specified in § 438.358; or

(iv) Have a present, or known future, direct or indirect financial relationship with an MCO or PIHP that it will review as an EQRO.

§ 438.356 State contract options.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities; and

(2) May contract with additional EQROs to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* The State, its agent that is not an MCO or PIHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(b) *Mandatory activities.* For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were underway during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) established by the State to comply with the requirements of § 438.204(g).

(c) *Optional activities.* The EQR may also use information derived during the preceding 12 months from the following optional activities:

(1) Validation of encounter data reported by an MCO or PIHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO or PIHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO or PIHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs or PIHPs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

§ 438.360 Nonduplication of mandatory activities.

(a) *General rule.* To avoid duplication, the State may use, in place of a Medicaid review by the State, its agent, or EQRO, information about the MCO or PIHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *MCOs or PIHPs reviewed by Medicare or private accrediting*

organizations. For information about an MCO's or PIHP's compliance with one or more standards required under § 438.204(g), (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) the following conditions must be met:

(1) The MCO or PIHP is in compliance with standards established by CMS for Medicare+Choice or a national accrediting organization. The CMS or national accreditation standards are comparable to standards established by the State to comply with § 438.204(g) and the EQR-related activity under § 438.358(b)(3).

(2) Compliance with the standards is determined either by—

(i) CMS or its contractor for Medicare; or

(ii) A private national accrediting organization that CMS has approved as applying standards at least as stringent as Medicare under the procedures in § 422.158.

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review applicable to the standards provided for in § 438.204(g); and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the standards for which the EQR will use information from Medicare or private accreditation reviews, and explains its rationale for why the standards are duplicative.

(c) *Additional provisions for MCOs or PIHPs serving only dually eligibles.* The State may use information obtained from the Medicare program in place of information produced by the State, its agent, or EQRO with respect to the mandatory activities specified in § 438.358 (b)(1) and (b)(2) if the following conditions are met:

(1) The MCO or PIHP serves only individuals who receive both Medicare and Medicaid benefits.

(2) The Medicare review activities are substantially comparable to the State-specified mandatory activities in § 438.358(b)(1) and (b)(2).

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare review from the activities specified under § 438.358(b)(1) and (b)(2) and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the mandatory activities for which it has exercised this option and explains its rationale for why these activities are duplicative.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO or PIHP from EQR if the following conditions are met:

(1) The MCO or PIHP has a current Medicare contract under part C of title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO or PIHP has been subject to EQR under this part, and found to be performing acceptably with respect to the quality, timeliness, and access to health care services it provides to Medicaid recipients.

(b) *Information on exempted MCOs or PIHPs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO or PIHP that it exempts from EQR the most recent Medicare review findings reported on the MCO or PIHP including—

(i) All data, correspondence, information, and findings pertaining to the MCO's or PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities;

(ii) All measures of the MCO's or PIHP's performance; and

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare+Choice deeming.*

(i) If an exempted MCO or PIHP has been reviewed by a private accrediting organization, the State must require the MCO or PIHP to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR produces at least the following information:

(1) A detailed technical report that describes the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO or PIHP. The report must also include the following for each activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained.

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's or PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid recipients.

(3) Recommendations for improving the quality of health care services furnished by each MCO or PIHP.

(4) As the State determines, methodologically appropriate, comparative information about all MCOs and PIHPs.

(5) An assessment of the degree to which each MCO or PIHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Availability of information.* The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO or PIHP, recipient advocacy groups, and members of the general public. The State must make this information available in alternative formats for persons with sensory impairments, when requested.

(c) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity of any patient.

§ 438.370 Federal financial participation.

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and EQR-related activities set forth in § 438.358 conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-

related activities conducted by any entity that does not qualify as an EQRO.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance)

Dated: August 6, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 3, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–1294 Filed 1–23–03; 8:45 am]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services
Centers for Disease Control and Prevention

42 CFR Part 493
Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Centers for Disease Control and Prevention

42 CFR Part 493

[CMS–2226–F]

RIN 0938–AK24

Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications

AGENCY: Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises and responds to comments on certain laboratory requirements issued pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. Specifically, this final rule sets forth requirements for certain quality control (QC) provisions and personnel qualifications; consolidates and reorganizes the requirements for patient test management, QC, and quality assurance; and changes the consensus required for grading proficiency testing challenges.

To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors.

EFFECTIVE DATES: This final rule is effective on April 24, 2003, except § 493.1443(b)(3) is effective on February 24, 2003.

Compliance Dates: To ensure a clear transition from the board certification provisions of the former rule at 42 CFR 493.1443(b)(2) that have a compliance date of December 31, 2002 (as set forth in 65 FR 82941), we will not be holding facilities out of compliance with the former rule until the effective date of the parallel provisions of this new rule to the extent that facilities are otherwise in compliance with the regulations for laboratory directors.

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen (CDC), (770) 488–8155, Judith A. Yost (CMS), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

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I. Background

On February 28, 1992, we published a final rule with comment period in the **Federal Register** (57 FR 7002) that set forth the requirements for laboratories that are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Under the provisions of the sentence following section 1861(s)(15) through 1861(s)(17) of the Social Security Act, (the Act) any laboratory that wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the Public Health Services Act. Subject to specified exceptions, all laboratories, regardless of whether they receive payment from the Medicare or Medicaid programs must have a current and valid CLIA certificate to test human specimens. The February 28, 1992 final rule with comment period established uniform requirements based on the complexity of testing performed by laboratories regardless of the laboratory's location, size, or type. In the interest of public health, we included requirements in the February 28, 1992 final rule with comment period to ensure the quality of laboratory services.

We recognized that it would take time and resources for laboratories to understand and to implement the new requirements contained in the February 28, 1992 final rule with comment period. This final rule completes the phase-in of certain requirements where the comments supported taking this action.

The phased-in provision included quality control (QC) requirements applicable to moderate complexity tests and the date by which an individual with a doctorial degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

During the phase-in, the Food and Drug Administration (FDA) was to establish a process to review and clear manufacturers' QC instructions for CLIA QC purposes. Because the CLIA program is user fee funded, we decided it would be prudent to wait until the phase-in period ended before implementing the FDA QC review. This afforded us the survey experience necessary to determine whether an additional FDA review process beyond that already in place as part of the premarket review would be of benefit to laboratories. We realized through our experience inspecting laboratories that an additional FDA review would not be of such benefit. We decided to remove this prospective provision. Therefore, we are removing all references to the FDA CLIA QC clearance process that was not implemented.

The phase-in effective dates contained in the February 28, 1992 final rule with comment period were further extended in the final rules with comment period published on December 6, 1994 in the **Federal Register** (59 FR 62606), May 12, 1997 in the **Federal Register** (62 FR 25855), October 14, 1998 in the **Federal Register** (63 FR 55031), and December 29, 2000 in the **Federal Register** (65 FR 82941).

The extensions allowed previously unregulated laboratories time to understand and implement these requirements. The extensions also provided the Department of Health and Human Services (HHS) additional time to issue revised QC requirements, review board certification program requests for approval, and ensure that laboratory directors with a doctoral degree had sufficient time to successfully complete the requirements for board certification.

On December 28, 2001, we published a proposed rule in the **Federal Register** (66 FR 67163) seeking comments on provisions to revise and expand the qualification requirements by which an individual with a doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution may qualify to serve as a director of a laboratory performing high complexity testing. The

three proposed alternative qualification pathways were as follows:

- On or after January 1, 2003, be certified and continue to be certified by a board approved by HHS.
- Before January 1, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least 2 years of laboratory training or experience, or both; and 2 years experience directing or supervising high complexity testing.
- Have at least 6 years of laboratory training or experience, or both, including 2 years of experience directing or supervising high complexity testing.

In this final rule, effective April 24, 2003, all laboratories must meet and follow the QC requirements. In addition, we are setting forth qualification requirements for an individual with a doctoral degree to serve as a director of a laboratory performing high complexity testing. Effective February 24, 2003, an individual with a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing if he or she is certified and continues to be certified by a board approved by HHS; or before the effective date of this rule, has served or is serving as a director of a laboratory performing high complexity testing and has acquired at least 2 years of laboratory training or experience, or both, and 2 years of experience directing or supervising high complexity testing.

The qualification requirements for high complexity laboratory directors that are contained in this final rule will become effective February 24, 2003. To ensure a smooth transition to these new provisions, we will not be holding facilities out of compliance with the Board certified regulations of the former rule until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the regulations for laboratory directors.

In addition, we are addressing the comments received in response to the February 28, 1992 final rule with comment period concerning part 493 of title 42 of the Code of Federal Regulations (CFR), subparts I, J, K, M, and P; comments received in response to the date-extension rules for certain provisions of subparts K and M; and comments to the December 28, 2001 proposed rule regarding qualification requirements for directors of laboratories performing high complexity testing.

II. Highlights and Organization of Final Rule

This regulation contains revisions to part 493 of title 42 of the CFR. We have renamed, reorganized, and consolidated similar requirements into one section, deleted duplicate requirements, and reworded numerous requirements to maintain and/or clarify their original intent, making the revised regulation easier to read and understand. In addition to specific changes to subparts I, J, K, M, and P, applicable technical and conforming changes were also made to other subparts.

The organization of this regulation now reflects the flow of a patient specimen through the laboratory, that is, from receipt of the specimen with the test request through test performance and test result reporting. In addition, this final rule more accurately describes the testing requirements and laboratory assessment activities.

In this final rule, the former Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests has been renamed Proficiency Testing Programs for Nonwaived Testing. In addition, in each specialty and subspecialty area of the subpart, we are restoring the requirement for the 80 percent agreement used by proficiency testing programs prior to the February 28, 1992 final rule with comment period.

The requirements formerly in Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; and Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests, are consolidated and reorganized into a new Subpart J—Facility Administration for Nonwaived Testing, and Subpart K—Quality Systems for Nonwaived Testing.

As revised by this issuance, subpart J consolidates and clarifies the facility administration requirements for laboratories performing nonwaived testing. These include requirements for facility space, utilities and safety, transfusion services, and record and specimen retention. Also, subpart J now specifies that laboratories must comply with Federal, State, and local laboratory requirements. This will allow CMS to support a Federal, State, or local government that seeks to protect the public from actions it finds would be detrimental to public health. In addition, the requirements formerly at § 493.1111 (now at § 493.1242(c)) have been revised to allow CLIA-certified laboratories to refer specimens to laboratories operated under the Veterans Administration (VA), the Department of Defense (DOD), and CLIA-exempt laboratories within a State whose licensure program has been granted approval under subpart E.

Requirements pertaining to the total testing process (preanalytic, analytic, and postanalytic) are now in subpart K. Specifically, subpart K has been revised to eliminate the QC requirements formerly at § 493.1202 and provisions pertaining to the FDA review and approval of manufacturers' test system QC for CLIA purposes as specified at § 493.1203 in the February 28, 1992 final rule with comment period. Also, subpart K is now structured to correlate with the movement of a specimen through the laboratory from acquisition to examination or testing, and reporting of results. The requirements were not substantively changed to correspond to the testing process, but we did eliminate redundant requirements and revise others for clarification.

In addition, subpart K now incorporates the requirements formerly in Subpart P—Quality Assurance; Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests. These requirements are now located under the appropriate sections in subpart K, that is, General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems. We listed the quality assurance (renamed quality assessment (QA) to more clearly reflect the activities performed) activities for each phase of testing. For example, QA requirements for preanalytic activities, such as monitoring the medical necessity and completeness of test request information solicited and obtained by the laboratory, now appear at the end of the preanalytic section of subpart K under § 493.1249. We believe that integrating the QA requirements into the various phases of the testing process enhances the understanding of the vital and important role QA plays in ensuring that quality services are provided by the laboratory throughout the entire testing process. To further emphasize and clarify the essential components of a comprehensive QA program, we are reiterating in each assessment section the laboratory's responsibility to: (1) Establish and follow written polices and procedures for an ongoing mechanism to monitor and assess each of its activities; (2) take corrective actions, as necessary, based on these assessments; (3) review the effectiveness of the assessments and corrective actions

taken; (4) revise policies and procedures, as necessary, to prevent recurrences of problems; (5) discuss the assessment activities and findings with the appropriate staff; and (6) document all assessment activities. To ensure the clarity of this final rule, many of the QA requirements from the former subpart P had to be rewritten.

To conform with the names of the new subparts I, J, and K, the former Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing has been renamed Personnel for Nonwaived Testing. In subpart M, we are finalizing the qualification requirements for directors of laboratories performing high complexity testing at § 493.1443(b)(3). In addition, we are revising § 493.1443(b)(3)(i) by removing the reference to specific boards approved by HHS. All HHS-approved boards are listed on the Internet at *http://cms.hhs.gov/clia/dirc/con.asp.* HHS-approved boards will also be listed in Appendix C of the State Operations Manual (CMS Pub. 7), subpart M. This change will allow greater flexibility to update the list of HHS-approved boards. Also, we are announcing two new HHS-approved boards; the National Registry for Clinical Chemistry at the doctoral level and the American Board of Forensic Toxicology.

To clarify these changes, we have provided a distribution table, which contains a detailed list of sections that have been removed or redesignated.

III. Distribution Table

The following crosswalk table enables the reader to easily locate where the requirements from the former rule have been relocated. It lists the former section titles along with the section titles as they appear in this final rule. In addition, the reorganized regulation now follows the path of patient specimens as they proceed through the clinical laboratory. This organizational structure was adopted at the recommendation of the Clinical Laboratory Improvement Advisory Committee to assist laboratories in better understanding the basic CLIA requirements.

TABLE.—CROSSWALK

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests:		
§ 493.1101—Introductory text	Specimen identification and integrity	§§ 493.1232;
	Preanalytic systems	493.1240;
	Postanalytic systems	493.1290
Procedures for specimen submission and handling:		
§ 493.1103(a)	Specimen identification and integrity	§§ 493.1232;
	Specimen submission, handling, and referral	493.1242(a)(1) through (a)(6);
	Procedure manual	493.1251(b)(1)
§ 493.1103(b)	Specimen submission, handling, and referral	§§ 493.1242(a)(8) and (d);
	Procedure manual	493.1251(b)(1)
§ 493.1103(c)	Removed	
Test requisition:		
§ 493.1105—Introductory text	Retention requirements	§§ 493.1105(a)(1);
	Test request	493.1241(a), (b), (c), and (d)
§ 493.1105(a)	Test request	§ 493.1241(c)(2)
§ 493.1105(b)	Test request	§ 493.1241(c)(1)
§ 493.1105(c)	Test request	§ 493.1241(c)(4)
§ 493.1105(d)	Test request	§ 493.1241(c)(6)
§ 493.1105(e)	Test request	§ 493.1241(c)(3) and (c)(7)
§ 493.1105(f)	Test request	§§ 493.1241(c)(3), (c)(5), and (c)(8)
	Specimen submission, handling, and referral	493.1242(a)(3)
Test records:		
§ 493.1107—Introductory text	Retention requirements	§§ 493.1105(a)(3);
	Specimen identification and integrity	493.1232;
	Test records	493.1283(a)(4) and (b)
§ 493.1107(a)	Test records	§ 493.1283(a)(1)
§ 493.1107(b)	Specimen submission, handling, and referral	§§ 493.1242(b);
	Test records	493.1283(a)(2)
§ 493.1107(c)	Test records	§ 493.1283(a)(3)
§ 493.1107(d)	Test records	§ 493.1283(a)(4)
Test report:		
§ 493.1109—Introductory text	Retention requirements	§§ 493.1105(a)(3)(ii), (a)(6)(i), (a)(6)(ii) and (b);
	Postanalytic systems	493.1290;
	Test report	493.1291(b), (c)(3), and (f)
§ 493.1109(a)	Confidentiality of patient information	§§ 493.1231;
	Postanalytic systems	493.1290;
	Test report	493.1291(a) and (c)(3)
§ 493.1109(b)	Test report	§§ 493.1291(c)(2), (c)(4), and (c)(6)
§ 493.1109(c)	Test report	§ 493.1291(c)(7)
§ 493.1109(d)	Test report	§ 493.1291(d)
§ 493.1109(e)	Test report	§ 493.1291(f)
§ 493.1109(f)	Procedure manual	§§ 493.1251(b)(13);
	Test report	493.1291(g)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§ 493.1109(g)	Test report	§ 493.1291(e)
§ 493.1109(h)	Test report	§ 493.1291(j)
Referral of specimens:		
§ 493.1111—Introductory text	Specimen submission, handling, and referral	§ 493.1242(c)
§ 493.1111(a)	Test report	§ 493.1291(i)(1)
§ 493.1111(b)	Test report	§ 493.1291(i)(2)
§ 493.1111(c)	Test report	§ 493.1291(i)(3)
General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests:		
§ 493.1201(a)	Removed	
§ 493.1201(a)(1)	Removed	
§ 493.1201(a)(2)	Facility Administration	§§ 493.1100
	General laboratory systems	493.1230
	Preanalytic systems	493.1240
	Analytic systems	493.1250
	Control Procedures	493.1256(d)
	Postanalytic systems	493.1290
§ 493.1201(b)	Analytic systems	§§ 493.1250;
	Procedure manual	493.1251(b)(7)
Moderate or high complexity testing, or both, Effective from September 1, 1992 to December 13, 2000:		
§ 493.1202(a)	Facility administration	§§ 493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§ 493.1202(b)	Facility administration	§§ 493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§ 493.1202(c)	Facility administration	§§ 493.1100;
	Subpart K—Quality systems for nonwaived testing.	493.1201 through 493.1227
§ 493.1202(c)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§ 493.1252(a);
	Maintenance and function checks	493.1254(a)(1) and (a)(2)
	Control procedures	493.1256(d)(2)
§ 493.1202(c)(2)	Procedure manual	§ 493.1251
§ 493.1202(c)(3)	Calibration and calibration verification procedures.	§ 493.1255
§ 493.1202(c)(4)	Control procedures	§ 493.1256
§ 493.1202(c)(5)	Control procedures	§ 493.1256(d)(1)
§ 493.1202(c)(6)	Corrective actions	§ 493.1282
§ 493.1202(c)(7)	Retention requirements	§ 493.1105(a)(3)
Moderate or high complexity testing, or both effective beginning 12/31/00:		
§ 493.1203—Introductory text	Removed	
§ 493.1203(a)	Removed	
§ 493.1203(b)	Removed	
Facilities:		
§ 493.1204—Introductory text	Facilities	§ 493.1101(a)
§ 493.1204(a)	Facilities	§§ 493.1101(a)(1) and (a)(2)
§ 493.1204(b)	Facilities	§ 493.1101(d)
Test methods, equipment, instrumentation, reagents, materials, and supplies:		
§ 493.1205—Introductory text	Facility Test systems, equipment, instruments, reagents, materials, and supplies.	§§ 493.1101(b); 493.1252
§ 493.1205(a)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(a)
§ 493.1205(b)	Facilities	§ 493.1101(b)
§ 493.1205(c)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)
§ 493.1205(c)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)
§ 493.1205(c)(1)(i)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)(1)
§ 493.1205(c)(1)(ii)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)(2)
§ 493.1205(c)(1)(iii)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)(3)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§ 493.1205(c)(1)(iv)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)(4)
§ 493.1205(c)(2)	Corrective actions	§ 493.1282(b)(3)
§ 493.1205(d)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(c)
§ 493.1205(d)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(c)(1)
§ 493.1205(d)(2)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(c)(2)
§ 493.1205(d)(3)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(c)(3)
§ 493.1205(d)(4)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(c)(4)
§ 493.1205(e)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(d)
§ 493.1205(e)(1)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§ 493.1252(d);
	Immunohematology	493.1271(b)
§ 493.1205(e)(2)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(e)
Procedure manual:		
§ 493.1211(a)	Procedure manual	§ 493.1251(a)
§ 493.1211(b)	Procedure manual	§ 493.1251(b)
§ 493.1211(b)(1)	Procedure manual	§ 493.1251(b)(1)
§ 493.1211(b)(2)	Procedure manual	§ 493.1251(b)(2)
§ 493.1211(b)(3)	Procedure manual	§§ 493.1251(b)(3);
	Histocompatibility	493.1278(d)(7)
§ 493.1211(b)(4)	Procedure manual	§ 493.1251(b)(4)
§ 493.1211(b)(5)	Procedure manual	§ 493.1251(b)(5)
§ 493.1211(b)(6)	Procedure manual	§ 493.1251(b)(6)
§ 493.1211(b)(7)	Procedure manual	§ 493.1251(b)(7)
§ 493.1211(b)(8)	Procedure manual	§ 493.1251(b)(8)
§ 493.1211(b)(9)	Procedure manual	§ 493.1251(b)(9)
§ 493.1211(b)(10)	Procedure manual	§ 493.1251(b)(10)
§ 493.1211(b)(11)	Procedure manual	§ 493.1251(b)(11)
§ 493.1211(b)(12)	Procedure manual	§ 493.1251(b)(12)
§ 493.1211(b)(13)	Specimen submission, handling, and referral	§§ 493.1242(a)(4);
	Procedure manual	493.1251(b)(1)
§ 493.1211(b)(14)	Procedure manual	§ 493.1251(b)(13)
§ 493.1211(b)(15)	Procedure manual	§ 493.1251(b)(14)
§ 493.1211(b)(16)	Procedure manual	§ 493.1251(b)(1)
§ 493.1211(c)	Procedure manual	§ 493.1251(c)
§ 493.1211(d)	Procedure manual	§ 493.1251(d)
§ 493.1211(e)	Procedure manual	§ 493.1251(d)
§ 493.1211(f)	Procedure manual	§ 493.1251(d)
§ 493.1211(g)	Retention requirements	§§ 493.1105(a)(2);
	Procedure manual	493.1251(e)
Establishment and verification of method performance specifications:		
§ 493.1213—Introductory text	Removed	
§ 493.1213(a)	Establishment and verification of performance specifications.	§ 493.1253(a)
§ 493.1213(b)(1)	Removed	
§ 493.1213(b)(2)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1) and (2)
§ 493.1213(b)(2)(i)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1) and (b)(2)
§ 493.1213(b)(2)(i)(A)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1)(i)(A) and (b)(2)(i)
§ 493.1213(b)(2)(i)(B)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1)(i)(B) and (b)(2)(ii)
§ 493.1213(b)(2)(i)(C)	Establishment and verification of performance specifications.	§ 493.1253(b)(2)(iii)
§ 493.1213(b)(2)(i)(D)	Establishment and verification of performance specifications.	§ 493.1253(b)(2)(iv)
§ 493.1213(b)(2)(i)(E)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1)(i)(C) and (b)(2)(v)
§ 493.1213(b)(2)(i)(F)	Establishment and verification of performance specifications.	§§ 493.1253(b)(1)(ii) and (b)(2)(vi)
§ 493.1213(b)(2)(i)(G)	Establishment and verification of performance specifications.	§ 493.1253(b)(2)(vii)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§ 493.1213(b)(2)(ii)	Establishment and verification of performance specifications.	§ 493.1253(b)(3)
§ 493.1213(c)	Establishment and verification of performance specifications.	§ 493.1253(c)
Equipment maintenance and function checks:		
§ 493.1215—Introductory text	Removed	
§ 493.1215(a)—Title only	Removed	
§ 493.1215(a)(1)	Removed	
§ 493.1215(a)(1)(i)	Removed	
§ 493.1215(a)(1)(ii)	Removed	
§ 493.1215(a)(2)—Lead-in only	Removed	
§ 493.1215(a)(2)(i)	Maintenance and function checks	§ 493.1254(b)(1)(i)
§ 493.1215(a)(2)(ii)	Maintenance and function checks	§ 493.1254(b)(1)(ii)
§ 493.1215(a)(2)(iii)	Maintenance and function checks	§ 493.1254(b)(1)(ii)
§ 493.1215(b)	Removed	
§ 493.1215(b)(1)	Removed	
§ 493.1215(b)(1)(i)	Removed	
§ 493.1215(b)(1)(ii)	Removed	
§ 493.1215(b)(2)	Removed	
§ 493.1215(b)(2)(i)	Maintenance and function checks	§ 493.1254(b)(2)(i)
§ 493.1215(b)(2)(ii)	Maintenance and function checks	§ 493.1254(b)(2)(ii)
§ 493.1215(b)(2)(iii)	Maintenance and function checks	§ 493.1254(b)(2)(ii)
Calibration and calibration verification procedures:		
§ 493.1217—Introductory text	General Provisions—Definitions Calibration and calibration verification procedures.	§§ 493.2; 493.1255
§ 493.1217(a)	Removed	
§ 493.1217(b)—Lead-in only	Removed	
§ 493.1217(b)(1)	Calibration and calibration verification procedures.	§ 493.1255(a)
§ 493.1217(b)(1)(i)	Calibration and calibration verification procedures.	§ 493.1255(a)(1)
§ 493.1217(b)(1)(ii)	Calibration and calibration verification procedures.	§ 493.1255(a)(2)
§ 493.1217(b)(1)(ii)(A)	Calibration and calibration verification procedures.	§ 493.1255(a)(2)(ii)
§ 493.1217(b)(1)(ii)(B)	Calibration and calibration verification procedures.	§ 493.1255(a)(2)(i)
§ 493.1217(b)(1)(iii)	Calibration and calibration verification procedures.	§ 493.1255(a)(3)
§ 493.1217(b)(2)	Calibration and calibration verification procedures.	§ 493.1255(b)
§ 493.1217(b)(2)(i)	Calibration and calibration verification procedures.	§ 493.1255(b)(1)
§ 493.1217(b)(2)(ii)	Calibration and calibration verification procedures.	§ 493.1255(b)(2)
§ 493.1217(b)(2)(ii)(A)	Calibration and calibration verification procedures.	§ 493.1255(b)(2)(i)
§ 493.1217(b)(2)(ii)(B)	Removed	
§ 493.1217(b)(2)(ii)(B)(1)	Removed	
§ 493.1217(b)(2)(ii)(B)(2)	Calibration and calibration verification procedures.	§ 493.1255(b)(2)(ii)
§ 493.1217(b)(2)(ii)(C)	Calibration and calibration verification procedures.	§ 493.1255(b)(3)
§ 493.1217(b)(2)(ii)(C)(1)	Calibration and calibration verification procedures.	§ 493.1255(b)(3)(i)
§ 493.1217(b)(2)(ii)(C)(2)	Calibration and calibration verification procedures.	§ 493.1255(b)(3)(ii)
§ 493.1217(b)(2)(ii)(C)(3)	Calibration and calibration verification procedures.	§ 493.1255(b)(3)(iii)
§ 493.1217(b)(2)(ii)(C)(4)	Calibration and calibration verification procedures.	§ 493.1255(b)(3)(iv)
§ 493.1217(b)(3)	Calibration and calibration verification procedures.	§ 493.1255(a) and (b)
Control procedures:		
§ 493.1218	Control procedures	§ 493.1256(a)
§ 493.1218(a)	Removed	
§ 493.1218(b)—Partial removed	Control procedures	§ 493.1256(b), (c)(1), and (c)(2)
§ 493.1218(b)(1)	Control procedures	§ 493.1256(d)(3)(ii)
§ 493.1218(b)(2)	Control procedures	§ 493.1256(d)(3)(i)
§ 493.1218(b)(3)	Control procedures	§ 493.1256(d)(5)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§ 493.1218(b)(3)(i)	Control procedures	§ 493.1256(d)(5)
§ 493.1218(b)(3)(ii)	Control procedures	§ 493.1256(d)(5)
§ 493.1218(b)(4)	Control procedures	§§ 493.1256(d)(3)(ii) and (d)(3)(iv)
§ 493.1218(b)(5)	Control procedures	§ 493.1256(h)
§ 493.1218(c)	Control procedures	§ 493.1256(d)(8)
§ 493.1218(d)	Control procedures	§ 493.1256(d)(10)(i)
§ 493.1218(d)(1)	Control procedures	§ 493.1256(d)(10)(ii)
§ 493.1218(d)(2)	Control procedures	§ 493.1256(d)(10)(iii)
§ 493.1218(e)	Control procedures	§ 493.1256(f)
§ 493.1218(f)	Control procedures	§ 493.1256(e)
§ 493.1218(f)(1)	Control procedures	§ 493.1256(e)(1)
§ 493.1218(f)(2)	Control procedures	§ 493.1256(e)(2)
§ 493.1218(f)(3)	Control procedures	§§ 493.1256(e)(3);
	Histopathology	493.1273(a)
§ 493.1218(f)(4)	Control procedures	§ 493.1256(e)(4)(5)
Remedial actions:		
§ 493.1219—Introductory text	Corrective actions	§ 493.1282(a) and (b)
§ 493.1219(a)	Corrective actions	§ 493.1282(b)(1)
§ 493.1219(a)(1)	Corrective actions	§ 493.1282(b)(1)(i)
§ 493.1219(a)(2)	Corrective actions	§ 493.1282(b)(1)(ii)
§ 493.1219(a)(3)	Corrective actions	§ 493.1282(b)(1)(iii)
§ 493.1219(b)	Corrective actions	§ 493.1282(b)(2)
§ 493.1219(c)	Test report	§ 493.1291(h)
§ 493.1219(d)	Test report	§ 493.1291(k)
§ 493.1219(d)(1)	Test report	§ 493.1291(k)(1)
§ 493.1219(d)(2)	Test report	§ 493.1291(k)(2)
§ 493.1219(d)(3)	Retention requirements	§§ 493.1105(a)(6);
	Test report	493.1291(k)(3)
Quality control records:		
§ 493.1221	Retention requirements	§ 493.1101(e);
		493.1105(a)(3)(i) through (a)(3)(ii);
	Test systems, equipment, instruments, reagents, material, and supplies performance.	493.1252(b);
	Establishment and verification of performance	493.1253(c);
	Maintenance and function checks	493.1254(a), (b)(1)(ii), and (b)(2)(ii);
	Calibration and calibration verification procedures.	493.1255(a) and (b);
	Control procedures	493.1256(g);
	Bacteriology	493.1261(c);
	Mycobacteriology	493.1262(c);
	Mycology	493.1263(c);
	Parasitology	493.1264(d);
	Virology	493.1265(b);
	Routine chemistry	493.1267(d);
	Hematology	493.1269(d);
	Immunohematology	493.1271(f);
	Histopathology	493.1273(f);
	Cytology	493.1274(h);
	Clinical Cytogenetics	493.1276(e);
	Histocompatibility	493.1278(g)
Quality control-specialties and subspecialties for tests of moderate or high complexity; or both:		
§ 493.1223	Control Procedures	§§ 493.1256(a), (b), (c), (d)(1), and (2);
Microbiology:		
§ 493.1225	Removed	
Bacteriology:		
§ 493.1227—Introductory text	Bacteriology	§ 493.1201
§ 493.1227(a)—Partially removed	Bacteriology	§ 493.1261(a)
Bacteriology:		
§ 493.1227(a)(1)—Partially removed	Control procedures	§§ 493.1256(d)(3)(ii), (d)(3)(iv), and (e)(1);
	Bacteriology	493.1261(a)(1)
§ 493.1227(a)(2)	Control procedures	§§ 493.1256(e)(1) and (e)(2);
	Bacteriology	493.1261(a)(2)
§ 493.1227(a)(3)	Bacteriology	§ 493.1261(a)(3)
§ 493.1227(b)	Control procedures	§ 493.1256(e)(1)
§ 493.1227(c)	Bacteriology	§ 493.1261(b)
§ 493.1227(c)(1)	Bacteriology	§ 493.1261(b)(2)
§ 493.1227(c)(2)	Bacteriology	§ 493.1261(b)(1)
Mycobacteriology:		
§ 493.1229—Introductory text	Mycobacteriology	§ 493.1202

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
§ 493.1229(a)	Mycobacteriology	§ 493.1262(a)
§ 493.1229(b)	Control procedures	§ 493.1256(e)(3)
§ 493.1229(c)	Control procedures	§§ 493.1256(e)(2);
	Mycobacteriology	493.1262(a)
§ 493.1229(d)	Mycobacteriology	§§ 493.1262(b)(1) through (b)(3)
Mycology:		
§ 493.1231—Introductory text	Mycology	§ 493.1203
§ 493.1231(a)	Control procedures	§§ 493.1256(e)(1) and (e)(4)
§§ 493.1231(b)	Control procedures	§ 493.1256(e)(1)
§ 493.1231(c)	Control procedures	§ 493.1256(e)(2)
§ 493.1231(d)	Mycology	§§ 493.1263(b)(1) through (b)(3)
Parasitology:		
§ 493.1233—Introductory text	Parasitology	§ 493.1204
§ 493.1233(a)	Parasitology	§ 493.1264(a)
§ 493.1233(b)	Parasitology	§ 493.1264(b)
§ 493.1233(c)	Parasitology	§ 493.1264(c)
Virology:		
§ 493.1235—Introductory text	Virology	§ 493.1205
§ 493.1235(a)	Facilities	§§ 493.1101(b);
	Test systems, equipment, instruments, reagents, material, and supplies.	493.1252(a)
§ 493.1235(b)	Virology	§§ 493.1265(b);
	Test records	493.1283(a)(4)
§ 493.1235(c)	Virology	§ 493.1265(a)
Diagnostic immunology:		
§ 493.1237	Removed	
Syphilis serology:		
§ 493.1239—Introductory text	Syphilis serology	§ 493.1207
§ 493.1239(a)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(a)
§ 493.1239(b)	Control procedures	§ 493.1256(d)(3)(iii)
§ 493.1239(c)	Control procedures	§§ 493.1256(a) and (d)(3)(ii);
§ 493.1239(d)	Control procedures	§ 493.1256(f)
§ 493.1239(e)	Immunohematology	§ 493.1271(b)
General immunology:		
§ 493.1241	General immunology	§ 493.1208
§ 493.1241(a)	Control procedures	§ 493.1256(d)(3)(iii)
§ 493.1241(b)	Control procedures	§ 493.1256(a)
§ 493.1241(c)	Control procedures	§ 493.1256(f)
§ 493.1241(d)—Lead-in only	Removed	
§ 493.1241(d)(1)	Immunohematology	§ 493.1271(b)
§ 493.1241(d)(2)	Immunohematology	§ 493.1271(b)
Chemistry:		
§ 493.1243	Removed	
Routine chemistry:		
§ 493.1245—Introductory text	Routine chemistry	§§ 493.1210; 493.1267
§ 493.1245(a)	Routine chemistry	§ 493.1267(a)
§ 493.1245(b)	Routine chemistry	§ 493.1267(b)
§ 493.1245(c)	Routine chemistry	§ 493.1267(b)
§ 493.1245(d)	Routine chemistry	§ 493.1267(c)
Endocrinology:		
§ 493.1247	Endocrinology	§ 493.1212
Toxicology:		
§ 493.1249—Introductory text	Toxicology	§§ 493.1213;
	Control procedures	493.1256(d)(4)
§ 493.1249(a)	Control procedures	§ 493.1256(d)(4)(i)
§ 493.1249(b)	Control procedures	§ 493.1256(d)(4)(ii)
Urinalysis:		
§ 493.1251—Introductory text only	Urinalysis	§ 493.1211
Hematology:		
§ 493.1253	Hematology	§ 493.1215
§ 493.1253(a)	Hematology	§§ 493.1269(a)(1) and (a)(2)
§ 493.1253(b)	Control procedures	§ 493.1256(d)
§ 493.1253(c)	Hematology	§ 493.1269(b)
§ 493.1253(d)	Hematology	§ 493.1269(c)
§ 493.1253(d)(1)	Hematology	§ 493.1269(c)(1)
§ 493.1253(d)(2)	Hematology	§ 493.1269(c)(2)
Pathology:		
§ 493.1255	Removed	
Cytology:		
§ 493.1257—Introductory text	Cytology	§ 493.1221

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§ 493.1257(a)	Cytology	§ 493.1274(b)
§ 493.1257(a)(1)	Cytology	§ 493.1274(b)(1)
§ 493.1257(a)(2)	Cytology	§ 493.1274(b)(2)
§ 493.1257(a)(3)	Cytology	§ 493.1274(b)(3)
§ 493.1257(a)(4)	Cytology	§ 493.1274(e)(4)
§ 493.1257(a)(5)	Cytology	§ 493.1274(a)
§ 493.1257(b)	Cytology	§ 493.1274(d)
§ 493.1257(b)(1)	Cytology	§§ 493.1274(d)(2) and (d)(2)(iv)
§ 493.1257(b)(2)	Cytology	§ 493.1274(d)(2)(iii)
§ 493.1257(b)(3)	Cytology	§ 493.1274(g)
§ 493.1257(b)(3)(i)	Cytology	§ 493.1274(d)(2)(i)
§ 493.1257(b)(3)(ii)	Cytology	§ 493.1274(d)(2)(ii)
§ 493.1257(c)	Cytology	§ 493.1274(e)(1)
§ 493.1257(c)(1)	Cytology	§§ 493.1274(e)(1)(i) through (e)(1)(v), and (e)(2)
§ 493.1257(c)(2)	Cytology	§ 493.1274(e)(3)
§ 493.1257(c)(3)	Cytology	§ 493.1274(d)(1)(i)(B)
§ 493.1257(c)(4)	Cytology	§ 493.1274(d)(1)
§ 493.1257(c)(4)(i)	Cytology	§§ 493.1274(d)(1)(i) and (d)(4)
§ 493.1257(c)(4)(ii)	Cytology	§ 493.1274(d)(1)(ii)
§ 493.1257(d)	Cytology	§ 493.1274(c)
§ 493.1257(d)(1)	Cytology	§ 493.1274(c)(1)
§ 493.1257(d)(1)(i)	Cytology	§ 493.1274(c)(1)(i)
§ 493.1257(d)(1)(ii)	Cytology	§ 493.1274(c)(4)
§ 493.1257(d)(1)(iii)	Cytology	§ 493.1274(c)(1)(ii)
§ 493.1257(d)(2)	Cytology	§ 493.1274(c)(2)
§ 493.1257(d)(3)	Cytology	§ 493.1274(c)(3)
§ 493.1257(d)(4)	Cytology	§§ 493.1274(c)(5)(i) through (c)(5)(vi)
§ 493.1257(d)(5)	Cytology	§ 493.1274(c)(6)
§ 493.1257(e)—Lead-in only	Removed	
§ 493.1257(e)(1)	Cytology	§ 493.1274(e)(4)
§ 493.1257(e)(2)	Cytology	§ 493.1274(e)(5)
§ 493.1257(f)	Cytology	§ 493.1274(e)(6)
§ 493.1257(g)	Retention requirements, Cytology	§§ 493.1105(a)(7)(i)(A); 493.1274(f)(2) through (f)(4)
Histopathology:		
§ 493.1259—Introductory text	Histopathology	§ 493.1219
§ 493.1259(a)	Histopathology	§ 493.1273(a)
§ 493.1259(b)	Retention requirements, Histopathology	§§ 493.1105(a)(7)(i)(B) and (a)(7)(ii); 493.1273(b)
§ 493.1259(c)	Facilities; Retention requirements, Histopathology.	§§ 493.1101(e); 493.1105(a)(7)(iii); 493.1273(b)
§ 493.1259(d)	Histopathology	§ 493.1273(d)
§ 493.1259(e)	Histopathology	§ 493.1273(e)
Oral pathology:		
§ 493.1261	Oral pathology	§ 493.1220
Radiobioassay:		
§ 493.1263	Radiobioassay	§ 493.1226
Histocompatibility:		
§ 493.1265—Introductory text	Histocompatibility	§ 493.1227
§ 493.1265(a)	Histocompatibility	§ 493.1278(f)
§ 493.1265(a)(1)	Histocompatibility	§ 493.1278(e)(2)
§ 493.1265(a)(1)(i)	Histocompatibility	§ 493.1278(e)(2)(i)
§ 493.1265(a)(1)(ii)	Histocompatibility; Procedure manual	§§ 493.1278(e)(1); 493.1251(b)(3)
§ 493.1265(a)(1)(iii)	Histocompatibility	§ 493.1278(e)(2)(ii)
§ 493.1265(a)(1)(iv)	Procedure manual	§§ 493.1251(b)(3) and (b)(13)
§ 493.1265(a)(2)	Histocompatibility	§ 493.1278(f)
§ 493.1265(a)(2)(i)	Histocompatibility	§ 493.1278(f)(2)
§ 493.1265(a)(2)(ii)	Histocompatibility	§§ 493.1278(d)(4) through (d)(5)
§ 493.1265(a)(3)—Lead-in only	Removed	
§ 493.1265(a)(3)(i)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b);
	Specimen submission, handling, and referral	§ 493.1242(a)(4)
§ 493.1265(a)(3)(ii)	Histocompatibility	§ 493.1278(a)(1)
§ 493.1265(a)(3)(iii)—Partially removed	Specimen identification and integrity, Histocompatibility; Test records.	§§ 493.1232; 493.1278(a)(2) 493.1283(a)(1)
§ 493.1265(a)(4)	Histocompatibility	§ 493.1278(a)(3)
§ 493.1265(a)(5)	Test systems, equipment, instruments, reagents, materials, and supplies.	§§ 493.1252(c)(1) through (c)(4)
§ 493.1265(a)(6)	Histocompatibility	§ 493.1278(b)
§ 493.1265(a)(6)(i)	Histocompatibility	§ 493.1278(b)(2)

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§ 493.1265(a)(6)(ii)	Histocompatibility	§ 493.1278(b)(3)
§ 493.1265(a)(6)(iii)	Histocompatibility	§ 493.1278(b)(5)(v)
§ 493.1265(a)(7)	Histocompatibility	§ 493.1278(b)(5)
§ 493.1265(a)(7)(i)	Histocompatibility	§ 493.1278(b)(5)(i)
§ 493.1265(a)(7)(ii)	Histocompatibility	§ 493.1278(b)(5)(ii)
§ 493.1265(a)(7)(iii)	Histocompatibility	§ 493.1278(b)(5)(iv)
§ 493.1265(a)(7)(iv)	Histocompatibility	§ 493.1278(b)(5)(iii)
§ 493.1265(a)(8)	Histocompatibility	§ 493.1278(d)
§ 493.1265(a)(8)(i)	Histocompatibility	§ 493.1278(d)(5)
§ 493.1265(a)(8)(i)(A)	Histocompatibility	§ 493.1278(d)(5)
§ 493.1265(a)(8)(i)(B)	Histocompatibility	§ 493.1278(d)(5)
§ 493.1265(a)(8)(ii)	Histocompatibility	§ 493.1278(d)(3)
§ 493.1265(a)(8)(ii)(A)	Histocompatibility	§ 493.1278(d)(3)
§ 493.1265(a)(8)(ii)(B)	Test systems, equipment, instruments, reagents, materials, and supplies.	§ 493.1252(b)
§ 493.1265(a)(9)—Lead-in only	Removed	
§ 493.1265(a)(9)(i)	Histocompatibility	§§ 493.1278(b)(6) and (d)(6)
§ 493.1265(a)(9)(i)(A)	Histocompatibility	§§ 493.1278(b)(6)(i) and (d)(6)(i)
§ 493.1265(a)(9)(i)(B)	Histocompatibility	§§ 493.1278(b)(6)(ii) and (d)(6)(ii)
§ 493.1265(a)(9)(i)(C)	Histocompatibility	§ 493.1278(b)(6)(iii)
§ 493.1265(a)(9)(ii)	Histocompatibility	§§ 493.1278(c) and (e)(3)
§ 493.1265(a)(10)	Histocompatibility	§§ 493.1278(a) and (f)
§ 493.1265(a)(11)	Immunohematology	§ 493.1271
§ 493.1265(a)(12)	Histocompatibility	§ 493.1278(a)(4)
§ 493.1265(a)(13)	Removed	
§ 493.1265(a)(14)	Histocompatibility	§ 493.1278(a)(5)
§ 493.1265(b)	Histocompatibility	§ 493.1278(f)
§ 493.1265(b)(1)	Histocompatibility	§ 493.1278(f)(1)
§ 493.1265(b)(2)	Histocompatibility	§ 493.1278(f)(1)
§ 493.1265(b)(3)	Histocompatibility	§ 493.1278(f)(3)
§ 493.1265(c)	Histocompatibility	§§ 493.1278(a) through (c)
§ 493.1265(d)	Immunohematology	§ 493.1271(b)
Clinical cytogenetics:		
§ 493.1267—Introductory text	Clinical cytogenetics	§ 493.1225
§ 493.1267(a)	Cytogenetics	§ 493.1276(c)
§ 493.1267(b)	Cytogenetics	§§ 493.1276(b)(1) through (b)(3)
§ 493.1267(c)	Cytogenetics	§ 493.1276(a)
§ 493.1267(d)	Cytogenetics	§ 493.1276(d)
Immunohematology:		
§ 493.1269—Introductory text	Immunohematology	§ 493.1217
§ 493.1269(a)	Immunohematology	§ 493.1271(a)(1)
§ 493.1269(b)	Immunohematology	§ 493.1271(a)(2)
§ 493.1269(c)	Immunohematology	§ 493.1271(a)(3)
§ 493.1269(d)	Immunohematology	§ 493.1271(a)
Transfusion services and bloodbanking:		
§ 493.1271—Partially removed	Requirements for transfusion services and Subpart M.	§ 493.1103; § 493.1449(b) and (q)
Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products:		
§ 493.1273—Introductory text	Immunohematology	§ 493.1271(b)
§ 493.1273(a)	Immunohematology	§ 493.1271(b)
§ 493.1273(b)	Immunohematology	§ 493.1271(b)
§ 493.1273(c)	Immunohematology	§ 493.1271(b)
§ 493.1273(d)	Requirements for transfusion services	§ 493.1103(c)(2)
Blood and blood products storage facilities:		
§ 493.1275(a)	Immunohematology	§ 493.1271(c)
§ 493.1275(a)(1)	Immunohematology	§ 493.1271(c)(1)
§ 493.1275(a)(2)	Immunohematology	§ 493.1271(c)(2)
§ 493.1275(b)	Requirements for transfusion services	§ 493.1103(c)(1)
Arrangement for services:		
§ 493.1277	Requirements for transfusion services	§ 493.1103(a)
Provision of testing:		
§ 493.1279—Partially removed	Requirements for transfusion services	§§ 493.1103(b)
Retention of samples of transfused blood:		
§ 493.1283	Immunohematology	§ 493.1271(d)
Investigation of transfusion reactions:		
§ 493.1285	Requirements for transfusion services; Immunohematology.	§§ 493.1103(d); 493.1271(e)(1)and (e)(2)

TABLE.—CROSSWALK—Continued

Former requirements and former sections (part 493, subparts J, K, M, and P)	Requirements in this final rule (part 493, subparts J, K, and M)	Sections in this final rule
Quality assurance for Moderate Complexity (including the Subcategory) or High Complexity Testing, or Any Combination of These Tests:		
§ 493.1701	Introduction; General laboratory systems; General laboratory systems assessment; Preanalytic Systems; Test request; Preanalytic systems assessment; Analytic Systems; Analytic systems assessment; Postanalytic Systems; Postanalytic systems assessment.	§§ 493.1200; 493.1230; 493.1239; 493.1240; 493.1241(e); 493.1249; 493.1250; 493.1289; 493.1290; 493.1299
Patient test management assessment:		
§ 493.1703—Introductory text	General laboratory systems; General laboratory systems assessment; Preanalytic Systems; Preanalytic systems assessment; Postanalytic Systems; Postanalytic systems assessment.	§§ 493.1230; 493.1239(a) and (b); 493.1240; 493.1249(a) and (b); 493.1290; 493.1299(a) and (b)
§ 493.1703(a)	Preanalytic systems assessment	§§ 493.1249(a) and (b)
§ 493.1703(b)	Preanalytic systems assessment	§§ 493.1249(a) and (b)
§ 493.1703(c)	Preanalytic systems assessment	§§ 493.1249(a) and (b)
§ 493.1703(d)	Postanalytic systems assessment	§§ 493.1299(a) and (b)
§ 493.1703(e)	Test Report; Postanalytic systems assessment.	§§ 493.1291(a), (g), and (h); 493.1299(a) and (b)
§ 493.1703(f)	Facilities; Postanalytic systems assessment	§§ 493.1101(e) 493.1299(a) and (b)
Quality control assessment:		
§ 493.1705—Introductory text	Analytic Systems; Analytic system assessment.	§§ 493.1250; 493.1289(a) and (b)
§ 493.1705(a)	Analytic system assessment	§§ 493.1289(a) and (b)
§ 493.1705(b)	Analytic system assessment	§§ 493.1289(a) and (b)
§ 493.1705(c)	Analytic system assessment; Postanalytic systems assessment.	§§ 493.1289(a) and (b); 493.1299(a) and (b)
Proficiency testing assessment:		
§ 493.1707	General laboratory systems; Evaluation of proficiency testing; General laboratory systems assessment.	§§ 493.1230; 493.1236(a)(1); 493.1239(a) and (b)
Comparison of test results:		
§ 493.1709		
§ 493.1709(a)	Comparison of test results	§ 493.1281(a)
§ 493.1709(b)	Evaluation of proficiency testing	§ 493.1236(c)(1)
Relationship of patient information to patient test results:		
§ 493.1711—Introductory text	Comparison of test results; Analytic systems assessment.	§§ 493.1281(b); 493.1289(a) and (b)
§ 493.1711(a)	Comparison of test results	§ 493.1281(b)(1)
§ 493.1711(b)	Comparison of test results	§ 493.1281(b)(2)
§ 493.1711(c)	Comparison of test results	§ 493.1281(b)(3)
§ 493.1711(d)	Comparison of test results	§ 493.1281(b)(4)
§ 493.1711(e)	Comparison of test results; Analytic systems assessment.	§§ 493.1281(b)(5); 493.1289(a) and (b)
Personnel assessment:		
§ 493.1713	Personnel competency assessment policies; General laboratory systems assessment.	§§ 493.1235; 493.1239(a) and (b)
Communications:		
§ 493.1715	Communications; General laboratory systems assessment.	§§ 493.1234; 493.1239(a) and (b)
Complaint investigations:		
§ 493.1717	Complaint investigations; General laboratory systems assessment.	§§ 493.1233; 493.1239(a) and (b)
Quality assurance review with staff:		
§ 493.1719	General laboratory systems assessment; Preanalytic systems assessment; Analytic systems assessment; Postanalytic systems assessment.	§§ 493.1239(b) and (c); 493.1249(b) and (c); 493.1289(b) and (c); 493.1299(b) and (c)
Quality assurance records:		
§ 493.1721	Retention requirements; General laboratory systems assessment; Analytic systems assessment.	§§ 493.1105(a)(5) and (b); 493.1239(c); 493.1249(c); 493.1289(c); 493.1299(c)

IV. Analysis and Responses to Public Comments

We received numerous comments on the final rule with comment period published on February 28, 1992 in the **Federal Register**. These comments were from State agencies, proficiency testing programs, professional organizations, the Clinical Laboratory Improvement Advisory Committee (CLIAC), laboratories, physicians, and the general public. Summaries of the public comments received and our responses to those comments are set forth below.

Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

We received a number of comments on the topic of proficiency testing. We intend to publish a notice of proposed rulemaking addressing proficiency testing issues in more detail in the future. We have, however, determined that it would be appropriate to include in this final rule a change that we believe is necessary to improve the operation of the CLIA proficiency testing program, related to the percentage of required agreement among participant or reference laboratories. Thus, we are addressing only one of the changes requested by the commenters and recommended by the CLIAC.

Specific comments received and response to comments regarding subpart I are set forth below.

Comment: A few commenters, professional organizations, and proficiency testing programs expressed their concerns over the change to a 90 percent consensus requirement to be reached before a proficiency testing sample could be graded. Commenters felt there should be a grade assigned to their samples. One commenter stated that their laboratory paid for samples, so grading should be required. Proficiency testing programs had similar opinions. The CLIAC recommended reducing the consensus required for grading proficiency testing challenges to decrease the number of ungradeable samples as ungraded proficiency testing is not effective in assisting laboratories in their quality assessment of test performance.

Response: We agree with the commenters and are changing the percentage of required agreement among participant or referee laboratories to 80 percent in the specialties and subspecialties where 90 percent agreement was previously required.

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

Following publication of the final rule with comment period, we received approximately 150 comments regarding subpart J. The comments were in response to the requirements for specimen submission and handling; test requisition including oral requests and authorized persons; and test records and test reports, including confidentiality and referral of specimens. The majority of the commenters disagreed with some portion of the requirements and some commenters requested clarification of certain requirements while others offered specific revised language.

Specific comments received and responses to comments regarding subpart J are set forth below.

Comment: A number of State agencies disagreed with our removal of the requirement that laboratories comply with applicable Federal, State, and local laws.

Response: We agree with the commenters and are reinstating the requirement now at § 493.1101(c). As part of the partnering relationship with State agencies and local governments, the reinstatement of this requirement will allow us to support a State or local government that seeks to protect the public from actions it finds would be detrimental to public health.

Comment: Some commenters disagreed with requiring written authorization for oral test requests, describing the difficulties that this requirement causes.

Response: We acknowledge that when a laboratory asks that an oral request for patient testing be followed with a written request, there is no guarantee that one will be received. On January 19, 1993, we published a technical correction in the **Federal Register** (58 FR 5215) and (58 FR 5229) that amended the requirement formerly at § 493.1105. This requirement, now at § 493.1241(b), states that oral requests for laboratory tests are permitted only if the laboratory requests written or electronic authorization for testing within 30 days of the oral request and documents the efforts made to obtain a written or electronic authorization.

Comment: We received several comments recommending information the laboratory should solicit and obtain on the test requisition. Specifically, the commenters believe the age and sex of the patient, time of specimen collection, and the specimen source should be included since they are pertinent to either how the laboratory processes the specimen and/or how the test results are interpreted.

Response: We agree with the commenters. The requirement, formerly at § 493.1105(f), requires the laboratory to ensure that the requisition or test authorization includes any additional information relevant and necessary for accurate and timely testing and result reporting (for clarity, we are adding ''interpretation'' if applicable to this requirement). The requirement, now at § 493.1241(c)(3), specifies that the laboratory must request the patient's sex and age or date of birth as normal values and interpretation of test results are often dependent on this information. Concurrently, we are redesignating age or date of birth requirements, formerly at § 493.1105(e), for Pap smear requisitions to test requests (now at § 493.1241(c)(3)). The time of specimen collection must also be requested when it is relevant for the testing to be performed. For example, this information is important when interpreting the results of peak and trough therapeutic drug assays. In addition, we are requiring that specimen source, when appropriate, be solicited on the test requisition. Specimen handling, preservation, and preparation (for example, use of proper transfer media, inoculation of media in microbiology and clinical cytogenetics, and the application of appropriate normal values reported with patient test results) are dependent on the origin of the specimen. Therefore, we are including specimen source, when appropriate, as part of the laboratory's submission, handling, and referral procedures (now at § 493.1242(a)(3)). We are also requiring specimen source to be included on the test report if warranted (now at § 493.1291(c)(5)). This routine laboratory practice was inadvertently omitted from the final rule with comment period.

Comment: One organization representing members of the laboratory community objected to the amount of information that a laboratory must have on the test requisition, specifically the information that is needed when submitting a Pap smear. The organization stated that laboratories do not have access to patient records and are dependent on the authorized person ordering the test to provide this information. The organization agreed the information was important but assumed we would prohibit testing if all information was not obtained by the laboratory.

Response: We agree with the commenter that the information being requested is important. Therefore, we are retaining the test request

requirements formerly at § 493.1105, (now at § 493.1241(c)) as relevant information necessary for proper test performance and interpretation. The test requisition requirements do not prohibit laboratories from performing the testing if the requested information is missing. Although we expect laboratories to obtain this information when possible, the potential negative impact of the missing information on the test results may be addressed or noted on the report.

Comment: One State health department requested modification of the requirement for recording the time of specimen receipt into the laboratory, stating we should require the time of receipt only if it is pertinent to sample integrity, test method, or procedure.

Response: We disagree with the commenter. Recording the date and time of specimen receipt enables the laboratory to determine the elapsed time between specimen receipt and reporting of patient test results. It also provides a mechanism to monitor transportation times for specimens referred to the laboratory. Therefore, we are retaining this requirement formerly at § 493.1107(b) (now at § 493.1242(b)).

Comment: One commenter stated the final rule with comment period did not require a person's name or unique identifier on the test report.

Response: We agree with the commenter that the final rule with comment period did not specifically require a patient's name or unique identifier as part of the test report formerly at § 493.1109. Therefore, we are adding at § 493.1291(c)(1), a requirement for the laboratory report to include the patient's name with an identification number, or a unique patient identifier and identification number to ensure positive patient identification. The patient's name alone is not a unique identifier, and when used on the test report, the patient's name must be accompanied by an identification or accession number. When a patient's name is not used for confidentiality purposes, or when the identity of the person is not known, a unique patient identifier must be submitted with the specimen. The laboratory must also use an identification number. In reviewing the report requirements formerly at § 493.1109(b), interpretation was omitted. Therefore, we are adding interpretation to the test report requirements at § 493.1291(c)(6) for those test results that require supplemental information.

Comment: Some commenters disagreed with requiring the name and address of the laboratory performing the test on the test report. They believed that too much information would make the report crowded and confusing. Another comment received from a professional organization acknowledged the benefit of this requirement, but stated its application to cumulative reports causes disruption of data presentation and utility of the report and, in some cases, the information cannot reasonably be included.

Response: We agree the name and address of the laboratory performing the test is an essential piece of information that must be included on the test report. It provides a contact for the individual who requested or is using the test results when additional information is needed for result interpretation and patient care. If a laboratory determines its reports are crowded or confusing, it has complete latitude and responsibility to reorganize the report in a manner that will correct the problem as specified formerly at § 493.1703 (now at § 493.1299). A laboratory that generates cumulative reports may use a single character identifier (for example, an asterisk or subscript) to identify a particular reference laboratory that performed the test. This information (the name and address of the reference laboratory) may be defined on a subsequent page or on the back of the report. Laboratories may develop other formats to meet this requirement. However, we are retaining the requirement formerly at § 493.1109(b) (now at § 493.1291(c)(2)) to include the name and address of the laboratory where the test was performed.

Comment: One commenter questioned the appropriateness of maintaining test records in the patient's chart or medical record.

Response: The CLIA regulation does not preclude laboratories from storing test records in a patient's chart or medical record; however, records must include the following:

- Test analysis (including instrument printouts, if applicable).
- Identity of the personnel performing the test.

To retain this type of information in a patient's chart or medical record may be cumbersome and impractical for QA activities; however, it is at the discretion of the laboratory.

Comment: One commenter questioned whether computer records of reports are acceptable in lieu of paper files.

Response: The requirement formerly at § 493.1109(h) specifies that all test reports or an exact duplicate of each test report must be maintained by the laboratory in a manner that permits ready identification and timely accessibility. The information contained on the test report may be manually written, generated by an electronic system, maintained on microfilm, or any other means, provided it contains all of the information that was on the original test report. Therefore, we are deleting the reference to ''exact duplicate'' that was contained in the former § 493.1109(h), and amending the language now at § 493.1291(j) to clarify that the laboratory must be able to retrieve a copy of the original report. We are also making a conforming change in the retention requirement for test reports (now at § 493.1105(a)(6)).

Comment: Many commenters stated that the removal of the subpart on laboratory information systems (LIS) was inappropriate and not logical considering the current and future direction of collection and dissemination of laboratory data. Other commenters indicated that the current method of reporting patient results and the laboratory computer system was overlooked.

Response: We agree with all of the commenters and are addressing some of the commenters' concerns pertaining to electronic patient and testing information by doing the following:

- Adding a requirement at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. Proper storage of patient records that are collected in a LIS is essential for record preservation and accurate recall of patient information. Without proper storage and maintenance of records, the timeframes, identification, and the accessibility of records will not be possible.
- Incorporating a requirement at § 493.1241(e) for laboratories using LIS to ensure that the requisition information is accurately transcribed or entered. The laboratory may establish its own mechanism to meet this requirement, possibly through random checks or representative sampling of LIS patient testing information verified against that submitted on the original test request.
- Adding a requirement at § 493.1291(a) that requires laboratories to ensure patient test results are accurately and reliably sent from the point of data entry to the final report's destination in a timely manner. We are providing frequently encountered reporting scenarios that must be reviewed by the laboratory to ensure the accuracy and reliability of the transmitted patient result information.
- Requiring at § 493.1291(c) that the date of the test report be identified on the report. This date must be maintained as the date testing results

were generated as a final report and must not change on copies reported at a later date.

The above requirements are intended to respond in part to the commenters' requests. We intend to publish, at a later date, a rule specific to laboratory information systems. For example, requirements for the establishment and verification of system programs, system security, system and device maintenance, system operator functions and responsibilities, and system backups.

Comment: One commenter was concerned about limited record storage space on-site and asked if off-site storage of records would be acceptable provided the laboratory was able to produce these records during an inspection.

Response: Records may be stored at a place of the laboratory's choosing providing the storage is appropriate and the laboratory can produce the documents within a reasonable time during the course of an inspection as required at § 493.1773(c).

Comment: Several commenters disagreed with the requirement to retain records for a minimum of 2 years or 5 years, depending upon the type of record. A professional organization questioned whether instrument printouts must be retained for 2 years if appropriate data are saved in a retrievable manner. Other commenters felt that 3 months, and, in one case, 6 months, would be sufficient time to retain instrument printouts.

Response: We believe all records related to testing, for example, records of test requests, patient test records including, if applicable, instrument printouts, and copies of test reports are essential for the ongoing QA reviews performed by the laboratory. Instrument printouts are test records and are sometimes used as test reports and for these reasons must be retained for the appropriate length of time unless all information is duplicated in another record system. Additionally, CLIA requires biennial certification that includes an inspection of the laboratory's activities for compliance with CLIA requirements by either an on-site inspection of the laboratory or a self-assessment inspection through use of the Alternate Quality Assessment Survey (AQAS). These inspections require a review of the testing performed by the laboratory since the previous biennial inspection. Two years is the minimum amount of time records must be retained to ensure that they are available for review at inspection. However, we are clarifying the record retention requirements for immunohematology and blood and blood products formerly at § 493.1107 introductory text and § 493.1221 (now at § 493.1105(a)(3)(ii)) and formerly at § 493.1109 introductory text (now at § 493.1105(a)(6)(i)) to ensure consistency with the FDA requirements for these types of records.

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

In the final rule with comment period, the QC rules are located in subpart K and include the general QC requirements and specific QC requirements for each specialty and subspecialty of testing. A phase-in period provided less stringent general QC requirements for unmodified moderate complexity tests approved by the FDA through the premarket notification 510(k) or premarket approval (PMA) process.

Following publication of the final rule with comment period, we received approximately 1,030 comments. Of these comments, 280 were directed at the general QC requirements, 67 pertained to the specialty and subspecialty QC requirements, and approximately 680 pertained to cytology and histopathology requirements. The majority of the comments disagreed with some portion of the requirements, indicating that the final rule with comment period was either too restrictive or too lenient. Some commenters requested clarification of certain requirements, while others offered specific revised language. A few comments agreed with the final rule with comment period, while others indicated the requirements had either been misinterpreted or misread. We addressed some of the commenters' issues in a technical correction published on January 19, 1993 in the **Federal Register** (58 FR 5215).

In evaluating the comments and considering the types of revisions to make in this subpart, we obtained recommendations from the CLIAC and consulted with various professional organizations and laboratory personnel. In September 1996, we participated in public discussions at a 2-day meeting in Atlanta, Georgia. At the public meeting, manufacturers, laboratory organizations, and State representatives made presentations concerning QC principles, control materials and systems, manufacturers' recommendations, costs associated with control testing, and personnel implications. Their recommendation was to make changes to accommodate new technology. Our changes in this final rule are based on the advice and comments we received.

Specific comments and response to comments regarding subpart K are set forth below.

Comment: We received mixed comments concerning the general QC requirements. Some commenters felt the QC requirements were burdensome and would increase the cost of testing and asked that these requirements be deleted or revised. Conversely, some commenters agreed with the requirements, indicating that QC is absolutely essential to producing accurate test results and is good laboratory practice. Others stated the requirements of subpart K were both reasonable and attainable. A few commenters requested further clarification.

Response: We agree with the comments that QC procedures are essential to good laboratory practice and production of accurate test results. Control procedures verify that the patient results are substantially unaffected by day-to-day variation caused by the test system, environment, or operator. While the requirement for implementing QC may initially increase the cost of testing in some settings, it may decrease the long term cost as improved accuracy and reliability of testing reduces the need for retesting and unnecessary procedures or treatments.

Comment: A manufacturer's organization requested that § 493.1202(c) be revised to include those products not subject to the FDA clearance process to allow laboratories performing these tests to meet the phase-in QC requirements.

Response: We agree that the regulation needs to be revised to include these products, and provisions addressing these products were added in the revisions to the regulations published in the January 19, 1993 technical corrections (58 FR 5215). Since these products are not evaluated by the FDA, they could not be included under § 493.1202(c) but were added to § 493.1202(b) and subject to all applicable standards of subpart K.

Comment: Comments were divided concerning the phase-in of the general QC requirements. Some commenters agreed with the phase-in while others were opposed. Some commenters felt that following manufacturers' instructions should be sufficient to meet the CLIA QC requirements. Others expressed concern that FDA would not complete the review and approval of manufacturers' QC instructions by September 1, 1994. Most commenters opposed the phase-in provision. Some

commenters were concerned that manufacturers' QC protocols cleared by the FDA might be less stringent than the CLIA QC requirements. Other commenters disagreed with having two sets of general QC requirements, and other commenters were confused about the phase-in requirements and requested clarification.

Response: We implemented a phase-in of the general QC requirements to allow previously unregulated laboratories performing only FDA-approved or cleared, unmodified, and moderate complexity testing sufficient time to implement effective QC programs. During the phase-in, the FDA was to establish a process to review and clear manufacturers' QC instructions for CLIA QC purposes. Under this process, laboratories could meet certain CLIA QC requirements by following the FDA-approved manufacturers' QC instructions. On four occasions, we extended the phase-in of the general QC requirements that are currently in effect until December 31, 2002. However, because the CLIA program is user fee funded, we decided it would be prudent to wait until the phase-in period ended before implementing the FDA QC review. This afforded us the survey experience necessary to determine whether an additional FDA review would be of benefit to laboratories. We realized through our experience inspecting laboratories that an additional FDA review would not be of such benefit. Therefore, in this final rule, we are eliminating the phase-in requirements and establishing minimum general quality system requirements applicable to all nonwaived testing, regardless of complexity. In addition, we are removing all references to the FDA QC clearance process that was not implemented. However, we agree with the commenters that it is essential for laboratories to perform testing according to the manufacturers' test system instructions as required formerly at § 493.1202(c)(1) (now at § 493.1252(a)).

Comment: A few comments were received in response to the environmental and safety requirements at § 493.1204. Some commenters indicated that the requirements were too lenient. Others were opposed to exempting moderate complexity testing from the requirements at § 493.1204 during the phase-in, stating that all laboratories should be subject to these requirements.

Response: We agree with the commenters and therefore are retaining the requirement formerly at § 493.1204 (now at § 493.1101, subpart J) and applying it to both moderate and high complexity testing. In addition, we are providing some flexibility to the requirement formerly at § 493.1204(b) (now at § 493.1101(d)) that requires laboratories to post safety precautions. The revisions now require that safety procedures be accessible rather than posted.

Comment: We received several comments concerning the requirements at § 493.1205. Most commenters opposed the requirement prohibiting the use of expired reagents. One commenter requested clarification of § 493.1205(c)(1) that requires the laboratory to define criteria for reagent and specimen storage conditions.

Response: We understand the concerns expressed regarding the use of rare and expensive reagents and materials beyond their expiration dates. However, the manufacturer has the responsibility for establishing expiration dates that ensure the reagents and materials will perform properly when used for patient testing. In addition, any changes in the labeling of *in-vitro* diagnostics must comply with Food, Drug, and Cosmetic Act requirements. Therefore, we are not making any revisions to the requirement formerly at § 493.1205(e)(1) (now at § 493.1252(d)) prohibiting the use of expired reagents and other materials.

In regard to licensed biological and blood products, any exceptions to dating requirements must be granted by the FDA in the form of an amendment to the product license. In this final rule, we are consolidating all requirements pertaining to the immunohematological testing and distribution of blood and blood products (now at § 493.1271(b)).

We are adding language to the requirement formerly at § 493.1205(c)(1) to clarify how the laboratory establishes and uses its criteria for storing reagents and patient specimens. The requirement now at § 493.1252(b), states that the laboratory must define criteria for those conditions in the manufacturer's test system instructions, when available, that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting. The criteria must be consistent with the manufacturers' instructions, if provided. These conditions must be monitored, documented, and include (1) water quality; (2) temperature; (3) humidity; and (4) electrical tolerances.

Comment: One commenter agreed with the requirements at § 493.1211, Procedure manual. Another commenter suggested that the procedure manual requirements be deleted. Two commenters opposed permitting the use of the manufacturer's package insert to satisfy the requirements at §§ 493.1211(b)(1) through 493.1211(b)(13). Another commenter suggested that laboratories be required to retain each procedure's original specifications and instructions for use as provided by the manufacturer, and maintain a list of any alterations or changes in the procedure manual.

Response: We disagree with the commenter who requested that the procedure manual requirements be deleted. All laboratories must maintain and follow procedure manual instructions in order to provide uniform patient testing. Therefore, we are retaining the requirements for a procedure manual now at § 493.1251. Laboratories may use the manufacturer's test system instructions to meet many of the procedure manual requirements, but must supplement them with any laboratory-specific information related to its testing and reporting practices. Examples are the laboratory's procedures for reporting patient test results, including panic values or alert values, corrective actions to follow when test systems become inoperable, and criteria for specimen referral. The use of the manufacturer's test system instructions to meet many of the procedure manual requirements is permitted to ensure that laboratories follow the manufacturer's instructions for patient testing and to minimize the burden on laboratories in developing procedure manuals.

For clarity and consistency, we are reiterating the requirements formerly at §§ 493.1103(a) and 493.1211(b)(14) (now at §§ 493.1242 and 493.1251) that the laboratory have written policies and procedures for specimen submission. In addition, we included language now at § 493.1251(b)(13) to clarify the use of laboratory information systems for entering patient test results.

In addition, we agree with the commenter that laboratories must have copies of test procedures. Therefore, we are retaining the requirement now at § 493.1251(e) that laboratories must maintain a copy of the procedure with the dates of initial use and discontinuance for 2 years after a procedure is no longer used.

Comment: Several commenters opposed the requirement at § 493.1211 for the director to approve, date, and sign the procedure manual, approve any change in procedure, or re-approve the manual should there be a change in directorship. One commenter suggested that the requirement be revised to state each procedure must be approved by the director before patient testing.

Response: The director is the individual ultimately responsible for the operation and administration of the

testing facility and is therefore responsible for authorizing all testing procedures and any alterations or revisions of these procedures. If a change in directorship occurs, re-approval of the manuals by the new director is necessary since he or she assumes responsibility for all testing procedures and any alterations or revisions of the procedures. We agree with the comment stating that each procedure should be approved by the director before patient testing. Therefore, we are revising the requirement formerly at § 493.1211(d) (now at § 493.1251(d)) to specify that the director reviews each procedure and change in procedure before use. We are also emphasizing that we do not expect laboratories to suspend testing for those procedures already in use that may not have been approved before patient testing. However, effective April 24, 2003, all alterations in current procedures and all newly implemented procedures must be reviewed and signed by the director before use.

In addition, we are revising the requirement formerly at § 493.1211(e) (now at § 493.1251(d)) to include the provision that requires procedures to be re-approved if the directorship changes. Section 493.1251(d) now states, ''procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.'' If the directorship changes, the current director would not be expected to suspend testing to review the procedures in use or changes to procedures approved by the previous director. However, the current director must review all procedures in use by the laboratory in a timely manner.

Comment: Approximately one third of the comments received disagreed with § 493.1213, Establishment and verification of method performance specifications. Some individuals opposed verifying the manufacturer's performance specifications for those methods cleared by FDA as meeting certain CLIA requirements for QC. One commenter disagreed with the requirement to establish performance specifications for those methods developed in-house, modified by the laboratory, or not cleared by FDA as meeting certain CLIA QC requirements. Another individual suggested that the standard be retroactive and apply to all test methods. One commenter asked that this standard be revised to state, ''The provisions of this section are not retroactive for previously unregulated laboratories. Previously unregulated laboratories are not required * * *.''

Response: We understand the commenters' concerns about the time and resources necessary to establish or verify performance specifications. However, these requirements ensure that the laboratory has either established test system performance specifications or verified that it can obtain the manufacturer's performance specifications in the laboratory's environment using the laboratory's testing personnel. In addition, establishment or verification of performance specifications are integral to the laboratory's establishment of appropriate and effective QC and calibration protocols. These protocols must include descriptions of the numbers, types, and concentrations of all calibration and control materials, as well as the performance intervals. Calibration and control protocols based on unverified performance specifications could result in poorly controlled and inaccurate testing. In the interest of establishing appropriate calibration and control practices and improving the reliability, accuracy, and usefulness of patient testing, we are retaining the requirements formerly at § 493.1213, and are now applying them to nonwaived testing at § 493.1253.

Laboratories employing methods (not modified by the laboratory) that have manufacturer-established performance specifications must demonstrate before reporting patient test results that they can obtain performance specifications for accuracy, precision, and reportable range of test results for the test system, comparable to those established by the manufacturer. The laboratory director must decide the extent to which these performance specifications are verified based on the method, testing conditions, and personnel performing the test.

In addition, we are clarifying when a laboratory must establish test system performance specifications (for example, laboratories using a test system in which the manufacturer does not provide performance specifications) now at § 493.1253(b)(2). Laboratories must, before reporting patient test results, establish, as applicable, performance specifications for the following performance characteristics: (1) Accuracy; (2) precision; (3) analytical sensitivity; (4) analytical specificity, including interfering substances; (5) reportable range of test results for the test system; (6) reference intervals (normal ranges); and (7) any other performance characteristic required for test performance.

Section 493.1253(b)(1) uses the term ''FDA-cleared or approved test system'' as defined (at § 493.2, Definition) in the November 9, 1997 revisions to the Food, Drug and Cosmetic Act (Pub. L. 105–115), to mean a test system cleared or approved by the FDA through either the premarket notification (510(k)) or premarket approval (PMA) process for *in-vitro* diagnostic use. This includes test systems exempt from FDA premarket clearance or approval.

Regulations do not have retroactive effect. The CLIA requirement's effective date became applicable to newly regulated laboratories on September 1, 1992. Those laboratories that were subject to regulations prior to this September 1, 1992 effective date were already required to validate test procedures under former Federal regulations before the CLIA requirements were implemented. This rule does not have a retroactive effect. Laboratories performing unmodified moderate complexity tests cleared or approved by the FDA are not required to retroactively verify the manufacturer's performance specifications. The results of the laboratory's control procedures, proficiency testing (required under subpart H) and assessment activities are used to verify test performance. However, as of April 24, 2003, laboratories must, before testing, either verify or establish performance specifications for any new test system.

Comment: Some commenters expressed approval of the requirements for the establishment and verification of a test system's method performance specifications before its use, and maintaining records of this activity while the test system is used for patient testing.

Response: We accept these positive comments and are retaining the requirements for the establishment and verification of method performance specifications formerly at § 493.1213 (now at § 493.1253). However, we realize the QC record retention requirements formerly at § 493.1221 may have been misinterpreted as permitting the laboratory to discard method performance specification records after a 2-year period even though the method may have continued to be used beyond this timeframe. Therefore, the analytic systems record retention requirement formerly at § 493.1221 (now at § 493.1105(a)(3)(i)) specifies that records of the laboratory's establishment and verification of method performance specifications must be retained for the period of time the test system is in use by the laboratory, but not less than 2 years. In addition, we are revising the original QC record retention requirement to accommodate the reorganization of the regulation and clarify its intent.

Comment: A few commenters disagreed in general with the

requirements at § 493.1215, Equipment maintenance and function checks. Other commenters requested clarification. One commenter felt that the requirements were too stringent, and another offered specific language for revision. One commenter felt CMS, not the manufacturer, should establish the frequency for performing function checks.

Response: Equipment maintenance and function checks are necessary to ensure accurate and reliable test performance. We are relocating the requirement formerly at § 493.1215 (now at § 493.1254) and renaming it Maintenance and function checks. Laboratories using unmodified manufacturers' equipment, instruments, or test systems must perform maintenance and function checks as defined by the manufacturer with at least the frequency specified by the manufacturer. Laboratories must also document maintenance and function checks performed. We are adding language at § 493.1254(a)(2) requiring that function checks be within the manufacturer's established limits before conducting patient testing. We are also retaining the present requirement (now at § 493.1254(b)) for laboratories to establish protocols that ensure proper test system performance, accurate and reliable test results and test reporting for equipment, instruments, or test systems developed in-house, commercially available but modified by the laboratory, or when protocols for maintenance and function checks are not provided by the manufacturer. In addition, laboratories must document the maintenance and function checks performed.

Under this final rule, we are not defining intervals for the performance of maintenance or function checks because the manufacturer is better able to define the appropriate procedures and intervals necessary to maintain and ensure proper equipment, instrument, and test system performance.

Comment: Several commenters suggested that § 493.1217, calibration and calibration verification, or substantially equivalent requirements, should also apply to FDA-approved or cleared, unmodified moderate complexity testing at § 493.1202(c). In addition, we received comments requesting clarification of § 493.1217. One commenter stated that CMS, not the manufacturer, should establish the frequency of calibration. A manufacturer commented that a loose interpretation of the calibration verification requirement to assay calibration materials in the same manner as patient samples is needed for certain blood gas analytes because buffers and gases used to calibrate the instruments are not like patient samples and cannot be assayed in the same manner as patient samples.

Response: We agree with the commenters and are specifying in this final rule that effective, April 24, 2003, calibration and calibration verification requirements (now at § 493.1255) will apply to all nonwaived testing.

To respond to the commenters' concerns that the calibration and calibration verification requirements are unclear, we are making some minor revisions in language for clarification purposes and removing duplicate requirements. For example, the definitions of calibration and calibration verification and reportable range are being slightly modified (now at § 493.2). We are also removing the requirement formerly at § 493.1217(b)(2)(ii)(B)(1) for laboratories to perform calibration verification using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value to allow laboratories flexibility in choosing materials for calibration verification.

In addition, we are retaining the requirement for laboratories, at a minimum, to perform calibration and calibration verification procedures using the manufacturers' test system instructions and the criteria verified or established by the laboratory formerly at §§ 493.1217(b)(1) and 493.1217(b)(2) (now at §§ 493.1255(a)(1), 493.1255(a)(2), 493.1255(b)(1) and 493.1255(b)(2)). We are also retaining the requirement that calibration must be performed whenever calibration verification procedures are unacceptable and calibration verification be performed using a minimum of 3 values to verify the laboratory's reportable range, at least once every 6 months or whenever an event occurs as specified formerly at § 493.1217(b)(2)(ii)(C) (now at § 493.1255(b)(3)).

In response to the comment that the frequency of calibration be mandated by CMS, we are retaining the requirement formerly at § 493.1217(b)(1) (now at § 493.1255(a)) that requires laboratories to calibrate according to the manufacturer's instructions, if provided, and the laboratory's specifications. We believe that laboratories should perform calibration at the interval specified by the manufacturer to ensure proper instrument and test system performance. For calibration verification formerly at § 493.1217(b)(2) (now at § 493.1255(b)), laboratories are to follow the manufacturer's specifications and the laboratory's established protocols for calibration verification that must be performed at least once every 6 months. We believe this is the maximum interval allowable for verifying accuracy and stability. In addition, we are emphasizing that these regulations set forth minimal requirements. In establishing or verifying performance specifications as required at § 493.1253, the laboratory may find it necessary to calibrate or verify calibration more frequently or to use more calibration materials than required at § 493.1255.

In response to the comment concerning the inability of testing calibration materials (buffers and gases) in the same manner as patient specimens when verifying the calibration of blood gas assays, we are retaining the additional requirements for routine chemistry formerly at § 493.1245 (now at § 493.1267) that supersede the general calibration and calibration requirements at § 493.1255. Section 493.1267(a) specifically addresses calibration and calibration verification of blood gas analyses and states the laboratory must calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. As long as the laboratory follows the manufacturer's calibration and calibration verification instructions for the blood gas instrument, the CLIA requirements for calibration and calibration verification are met.

Comment: We received many comments concerning various components of § 493.1218, Control procedures. Some commenters misread the CLIA regulation, and others offered specific language for revision. Most commenters opposed testing two levels of control material each day of use. One commenter indicated that the CLIA requirements are burdensome and will increase the cost of testing. Some commenters expressed concern that the requirements are arbitrary and do not recognize unit use test systems. Another commenter asked if procedural controls may be used to satisfy the control requirements.

Response: We appreciate the commenters' concerns about the frequency and costs of performing control testing. However, CLIA regulations will continue to describe the purpose of control procedures, that is, to assess the accuracy and precision of test performance. The control procedures must monitor the complete analytical process by detecting immediate errors (those that occur due to test system failure, adverse environmental conditions or operator performance problems) and monitor over time the accuracy and precision of test performance that can be influenced by

subtle changes in test system performance, environmental conditions, and variance in operator performance (for example, different operators and same operator variations in specimen handling and testing).

In response to the comments concerning unit use test systems and the use of procedural controls, we are making allowances for the use of procedural controls in Appendix C of the State Operations Manual (CMS Pub. 7) when equivalent quality procedures can be demonstrated.

In addition, we are providing a definition for test system (now at § 493.2). A test system is the instructions and all of the instrumentation, equipment, reagents, and/or supplies needed to perform an assay or examination and generate test results.

A control material must detect errors in the entire testing process. It must also monitor the quality of the results provided by the test system. It may be supplied by the test system manufacturer or another source. We are also relocating the requirement for control materials to be tested in the same manner as patient samples formerly at § 493.1218(c) (now at § 493.1256(d)(8)) and clarifying that this requirement applies to control materials and that over time control testing must be rotated among all operators who perform the testing (now at § 493.1256(d)(7)).

We are reducing the frequency of testing control materials from ''each run'' to ''each day of testing.'' We are retaining the former requirements for qualitative procedures (test positive and negative control materials) and quantitative procedures (test two levels of control material). For test procedures producing graded or titered results, we are relocating the requirement to test a negative control and a control of graded or titered reactivity from Syphilis serology and General immunology formerly at §§ 493.1239(b) and 493.1241(a), respectively (now at § 493.1256(d)(3)(iii)).

As part of updating the requirements for new technology and test methodologies formerly at § 493.1218(b)(3) (now § 493.1256(d)(5)), we are revising the wording of the control requirement for electrophoresis procedures.

Comment: One commenter urged that we remove specific stipulations for frequencies of performing QC or calibrations and substitute reference to an agency or professional association guidelines. The commenter also recommended that we accept alternate approaches suggested by a manufacturer as documented in test system instructions approved by the FDA. Another commenter suggested that § 493.1218(a) be revised to state, ''that the laboratory should run controls as specified by the manufacturer's instructions.'' Several commenters and one organization stated it is the laboratory director's responsibility to design the control system needed to achieve the desired quality.

Response: We consider the requirements established in subpart K as the minimum control measures needed to ensure accurate and reliable test results. According to the requirements formerly at § 493.1213 (now at § 493.1253), each laboratory must verify or establish a test system's method performance specifications and use this information in determining appropriate calibration and control protocols. This may include more frequent testing and greater numbers of materials than specifically provided under CLIA regulations. For example, the laboratory is required to perform calibration and control procedures in the manner necessary to ensure quality results. In cases where the manufacturer's instructions require more stringent testing of calibrators, control materials, or both, the laboratory is required to follow the manufacturer's instructions. Therefore, we are clarifying that laboratories must follow the manufacturer's instructions for control testing if they meet or exceed the requirements now at § 493.1256(d)(3).

We agree with the comment concerning the laboratory director's responsibility to determine appropriate control procedures to monitor the complete analytical process. This requirement is specified in CLIA regulations under the director's responsibilities at § 493.1407(e)(5) for moderate complexity testing and § 493.1445(e)(5) for high complexity testing.

Comment: A commenter suggested that acceptable control materials are two samples of different concentrations of controls or two concentrations of calibration material of a different lot other than the lot used for assay calibration, or any combination that results in both normal and abnormal values.

Response: We agree with the commenter and emphasize that any calibrator used as control material must be of a different lot number than the one(s) used to establish a cutoff value or calibrate the assay. Therefore, we are revising this requirement formerly at § 493.1218(b)(2)(now at § 493.1256(d)(9)) to clarify that the calibrators used as control materials must be of different concentrations than the calibrators employed to set instrumentation. We recommend that the acceptable range of control materials reflect some clinical decision points, both normal and abnormal.

Comment: One commenter suggested that § 493.1218(d) be revised to include a provision that if the performance specifications at § 493.1213 are exceeded, the laboratory must take corrective action before patient testing can continue.

Response: We agree with the commenter. The requirements formerly at § 493.1219(a) (now at § 493.1282(b)(1)) require corrective action, and the requirements formerly at § 493.1701 (now at § 493.1289(b)) require the laboratory to review the effectiveness of its corrective actions and, if necessary, revise policies and procedures to prevent recurring problems.

Comment: One commenter disagreed with the requirement to check each batch or shipment of media.

Response: The CLIA regulations allow laboratories to use the manufacturer's QC checks of certain media, provided the manufacturer's product insert specifies that the manufacturer's QC checks meet the NCCLS standards for media QC formerly at § 493.1218(f)(4), now addressed in Appendix C of the State Operations Manual (CMS Pub. 7). For media not included by NCCLS, we believe it is critical that the laboratory check each batch of media to ensure that it is not contaminated, supports growth of appropriate organisms, and elicits the correct biochemical response(s). The former § 493.1218(f)(4) (now § 493.1256(e)(4)) clarifies that media checks must be performed before, or concurrent with, initial use of media.

Comment: A few commenters expressed disagreement with the requirement to evaluate the detection phase of direct antigen systems and the extraction phase when it is included.

Response: We believe the laboratory must verify that all steps of a testing procedure are functioning properly to prevent erroneous results. Therefore, we are retaining the requirement formerly at § 493.1218(b)(4) (now at § 493.1256(d)(3)(iv)) that requires laboratories to test two control materials, one that is capable of detecting errors in the extraction phase.

Comment: One commenter agreed with requiring the determination of statistical parameters for each lot of calibration or control materials.

Response: We are retaining the requirement formerly at § 493.1218(d)(2) (now at § 493.1256(d)(10)(i)) for laboratories to have statistical

parameters for each lot of control material. In addition, we are clarifying that the requirement applies to controls with quantitative results. When calibration materials (not used to establish a cutoff value or calibrate the test system) are used as control materials, the laboratory must have statistical parameters for each lot of calibration material.

Comment: Some comments received were in reference to § 493.1219, Remedial actions. One commenter requested clarification and another requested deletion of § 493.1219(a)(2) that requires the laboratory to document all remedial action taken when patient test results are outside of the laboratory's reportable range for the test system. One individual asked for clarification of § 493.1219(d)(3) that requires the laboratory to maintain exact duplicates of both original and corrected reports for 2 years when errors in the reported test results are detected. One commenter suggested that no patient results that are less than the lowest calibrator or higher than the highest calibrator can be reported unless they are reported as less than or greater than the lowest or highest calibrator or the patient specimen is diluted to determine a higher value.

Response: The requirement formerly at § 493.1219(a)(2) (now at § 493.1282(b)(1)(ii)) requires documentation of all remedial actions (now ''corrective'' actions) when patient values are outside of the laboratory's reportable range of patient test results. The documentation can be an instrument printout or other document that reflects the problem, corrective action, and outcome. The laboratories must retain this information for the required period and the corrective actions themselves may be as elementary as diluting and retesting the specimen. We are not making any revisions to this requirement.

The requirement formerly at § 493.1219(d)(3) (now at § 493.1105(a)(6)) requires the laboratory to maintain a copy of the original report, or be able to retrieve a copy of the original report and the corrected report for 2 years. Copies of test reports may be manually written, photocopies, electronically generated, or maintained on microfilm provided they contain all of the information supplied on the original test record or report.

We agree with the suggestion that results outside of the reportable range of the test system may not be reported without corrective action or explanatory remarks. Therefore, requirements formerly at § 493.1219 (now at § 493.1282, Corrective actions) require laboratories to have corrective action policies and procedures that are followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This includes policies governing the reporting of patient results that exceed the reportable range of the test system. The analytic assessment requirements at § 493.1289 require the laboratory to monitor and evaluate the corrective actions taken and revise policies and procedures as necessary to prevent recurrences of problems.

Comment: One commenter suggested that CLIA rules require all original worksheets and instrument printouts to be retained for 6 months, indicating that some laboratories destroy, delete, or erase records of unacceptable QC in order to avoid showing remedial action and reassessment of all patient tests results associated with the failure.

Response: We understand the concerns expressed by the commenter. However, we believe the CLIA regulations adequately address documenting all control procedures performed formerly at § 493.1221 (now at §§ 493.1256(g) and 493.1105(a)(3)), maintaining records of all control procedures performed formerly at § 493.1221 (now § 493.1105(a)(3)), assessing corrective actions taken formerly at § 493.1705 (now at §§ 493.1289(a) and (b)) and retention of the original worksheets and instrument printouts for a period of 2 years or more formerly at § 493.1107 (now at § 493.1105(a)(3)). We also believe that if the laboratory deletes or alters a control result in any manner, it is expected that the laboratory will document the exact circumstances in which deletion or alteration occurred and document all corrective actions taken to prevent reoccurrence.

Comment: One commenter felt that there should be a requirement that any abnormal, life-threatening, or panic value result obtained on a moderate complexity test should be repeated by a more accurate method of testing.

Response: The requirement formerly at § 493.1109(f) (now at § 493.1251(b)(13)) requires laboratories to develop written procedures for reporting life-threatening results (panic or alert values). In addition, under the requirement formerly at § 493.1109(f) (now § 493.1291(g)) laboratories must immediately alert the individual or entity that requested the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition. In addition, it is the responsibility of each laboratory to ensure that the results it reports are accurate. Repeat testing is one method of verifying the test results. However, it is up to each laboratory to determine the protocols it will follow to confirm the test results that it reports.

Section 493.1223 Condition: Quality Control-Specialties and Subspecialtes for Tests of Moderate or High Complexity, or Both

Specific comments received and response to comments regarding § 493.1223, specialty or subspecialty control requirements are set forth below.

Comment: One commenter stated that the specialty and subspecialty QC requirements are too lenient.

Response: The specialty and subspecialty QC requirements are minimum requirements that reflect good laboratory practice and must be followed by all laboratories performing nonwaived testing. However, based on the laboratory's establishment and verification of its test systems' performance specifications (now at § 493.1253), the laboratory may determine that, to ensure accurate and reliable test results, it must implement more stringent control procedures than the minimum requirements imposed. In addition, it is the laboratory director's responsibilities to ensure that the laboratory has systems that ensure the quality of the laboratory services provided and identify failures in quality as they occur (§§ 493.1407(e)(5) and 493.1445(e)(5)).

Comment: One commenter disagreed with § 493.1223 stating a laboratory could lose approval to perform testing in an entire specialty or subspecialty if it is deficient in performing QC for a single test. The commenter urged that the language be changed to ''Failure to satisfy requirements for an individual test or analyte would result in loss of approval for that test or analyte only.''

Response: We emphasize that CLIA certification of laboratories is not granted on a test-by-test basis, but by specialty or subspecialty of testing. Therefore, if a laboratory has significant problems related to only one test or analyte in a specialty or subspecialty and the laboratory fails to correct those problems, it could jeopardize its certification for the specialty or subspecialty area. For example, the laboratory is notified in writing of the deficiencies found during a survey and is given an opportunity to correct the deficiencies. If the laboratory does not correct the deficiencies, sanctions could be imposed as specified in Subpart R—Enforcement Procedures. Therefore, we are deleting the enforcement

information formerly at § 493.1223 because subpart R contains this information. In addition, revocation of specialty or subspecialty certification for problems related to a particular test would be taken only as a last resort.

Sections 493.1225 Condition: Microbiology; 493.1227 Condition: Bacteriology; 493.1229 Condition: Mycobacteriology; 493.1231 Condition: Mycology; 493.1233 Condition: Parasitology; and 493.1235 Condition: Virology

Specific comments received and response to comments regarding §§ 493.1225, 493.1227, 493.1229, 493.1231, 493.1233, and 493.1235 are set forth below.

Comment: A professional organization, the American Society for Microbiology (ASM), commented that the CLIA QC requirements should be revised over time as new information is made available about the performance parameters of reagents or test systems. At a CLIAC meeting, this organization presented data on control failures for commercial microbiology reagents and stains and suggested that the current frequencies for control testing of a number of microbiology tests or reagents are excessive. ASM collected the data via two surveys of 304 clinical microbiology laboratories that perform varying levels of microbiological testing. It included failure rates for a total of 14,731 lots of reagents and stains, representing 21 different tests. Reagents and stains for 11 of the tests surveyed currently have control testing frequencies specified in the CLIA regulations: catalase, oxidase, coagulase plasma, *Salmonella* antisera, *Shigella* antisera, Gram stain reagents, optochin, bacitracin, Cefinase™ (beta lactamase), X and V factor strips and disks, and germ tube test. In this final rule, specific control testing frequencies are not given for eight reagents (spot indole, staphylococcal latex reagents, streptococcal latex grouping reagents, PYR disks, deoxycholate, KOH (fungal), LAP disks, and ALA) and two stains (lactophenol cotton blue and methylene blue). Based on the results of their surveys, the ASM proposed that laboratories should only be required to test new lot numbers of those commercial microbiology reagents that had a 98 percent or greater success rate (all reagents they surveyed met this requirement). In addition to testing each new lot, ASM recommended that laboratories test *Salmonella* and *Shigella* antisera every 6 months thereafter. ASM recommended that for epidemiological testing conducted in public health laboratories, the frequency for testing Salmonella and Shigella antisera should be determined by the periodicity supported by each laboratory's data.

In making this presentation, ASM stated that the changes they were proposing would improve the cost effectiveness of the CLIA program and quality assurance programs in clinical laboratories without compromising public health. The CLIAC supported the proposal and recommended the incorporation of these changes into the CLIA regulations.

Response: We appreciate the efforts of ASM, and the data they provided. The survey results provided the supporting information and data needed to revise the control testing frequency requirements. Based on the low failure rates for the commercial microbiology reagents surveyed, we agree it is adequate to test the majority of these reagents with each batch (prepared in-house), lot number (commercially prepared), and shipment when prepared or opened for positive, negative, and graded reactivity, as applicable. We also agree with checking antisera initially and once every 6 months thereafter except for epidemiological testing that is not subject to CLIA.

For two of the stains surveyed, the Gram stain and methylene blue, we do not agree that the low failure rate of the reagents is sufficient reason to decrease the stringency of the control requirements. The Gram stain procedure uses several reagents and has multiple steps that require specific timing for accurate results. Also, interpretation of the stained smear requires individual skill and expertise. By decreasing the frequency of control testing for this procedure to once every batch, lot number, and shipment, small laboratories that perform only rare Gram stains on direct specimens may not test controls for a period of months. We do not believe this is appropriate for a critical test used, in some cases, to presumptively diagnose an infectious disease (for example, direct smear for *Neisseria gonorrhoeae*). For this reason, we are maintaining the current weekly control testing requirement for Gram stain in addition to testing with each new batch, lot number and shipment.

Similar to the Gram stain usage in small laboratories, methylene blue stains may not be performed for an extended period of time, especially in laboratories that do not routinely use this staining procedure. We do not believe it is overly burdensome to require control testing of this stain each day of use.

In making the revisions discussed above, we deleted the specific control requirements for the reagents surveyed by ASM in the subspecialties of bacteriology formerly at § 493.1227 (now at § 493.1261) and mycology formerly at § 493.1231 (now at § 493.1263), except for requiring in bacteriology that the Gram stain be tested each week of use, and antisera be tested when each batch, lot number, and shipment is prepared or opened, and once every 6 months thereafter. We are also requiring in mycology that the laboratory check each batch, lot number, and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with control organisms. Additional control testing for lactophenol cotton blue is not required. The required control testing frequencies for other reagents and stains will default to the general control procedures requirements formerly at § 493.1218(f) (now at § 493.1256(e)(1) and (2)). The general control requirements for reagents include testing each batch (prepared in-house), lot number (commercially prepared) and shipment when prepared or opened. The general control requirements for stains (for example, methylene blue) include testing staining materials for intended reactivity each day of use. As indicated by ASM, we believe these changes will decrease the cost of microbiology testing, without significantly affecting the quality of the test results.

The CLIAC requested further input from ASM on appropriate control requirements for microbiology. ASM submitted the following recommendations based on consultation with clinical microbiologists:

- The mycology requirement (for auxanographic media for nitrate assimilation) to check the nitrate reagent each day of use with a peptone control is not relevant since most laboratories no longer perform this test for fungal identification. This requirement could be deleted, and if laboratories do use the procedure, it would be sufficient to perform control testing with each batch or lot.
- The requirement for parasitology laboratories to check permanent stains, each month of use, with a fecal sample should be changed to ''with a fecal sample or commercial QC slide.''
- To control the decontamination process for mycobacteriology culture specimens, process a specimen containing *Mycobacterium fortuitum* with each new lot number or batch of decontaminating agent.
- The frequency of control testing should be standardized for all microbiology subspecialties. Although there has been no data collected for reagents or stains used in subspecialties

other than bacteriology, ASM suggested that it was their experience that these reagents and stains perform as well as the reagents surveyed for bacteriology.

• Molecular amplification control procedures should adhere to standards outlined in the NCCLS document ''Molecular Diagnostic Methods for Infectious Diseases, MM3–A, 1995.'' At a minimum, control procedures for these tests should validate cell lysis, absence of inhibitors, absence of contamination, and adequate amplification. The following controls should be included with each run:

• Positive control (low range of assay sensitivity).

• One to five negative controls.

• Internal control.

• Quantitative assays should include two to three standards of known copy number. For microbial genotyping, control procedures should include at least two isolates of the same species being tested. One isolate should have the same phenotype as the unknown, and one should be a different phenotype.

Response: Our responses to the above recommendations are set forth below.

We agree that the mycology requirement for control testing of nitrate assimilation on auxanographic media is not relevant for the large majority of laboratories performing fungal identification, and have deleted that requirement. If laboratories use the procedure, they will be required, as stated formerly at § 493.1218(f) (now at § 493.1256(e)(1)) to test the medium and reagents with each batch (prepared in-house), lot number (commercially prepared), and shipment when prepared or opened. This will be the same control testing as required for other reagents and media used for fungal identification procedures.

The language formerly at § 493.1233(c) (now at § 493.1264(c)) requires laboratories to check permanent stains each month of use by using a fecal sample control. This terminology does not preclude the use of a fecal sample as a control or a commercially prepared control slide. The requirement remains as written in existing CLIA regulations; however, we will note this clarification in Appendix C of the State Operations Manual (CMS Pub. 7).

We recognize ASM's concern that the mycobacteriology decontamination process be monitored and adequately controlled to ensure that the decontaminating agent is of the proper strength to kill contaminating organisms without destroying mycobacteria (especially *Mycobacterium tuberculosis*). However, the method they suggested for doing this is only one way in which it may be accomplished. There are a number of other ways in which this process may be controlled (for example, monitoring the contamination rate over time to ensure the appropriate organisms are being killed). In an effort to maintain flexibility in CLIA regulations, in this final rule, we are not adding this ASM proposed control requirement to those for mycobacteriology. As noted formerly at § 493.1103(a) (now at § 493.1232), the laboratory must establish and follow written policies and procedures that assure optimum integrity of patient specimens from the time they are collected until testing has been completed and results reported. In addition, former § 493.1103(a) (now at § 493.1242(a)(6)) requires laboratories to have and follow written policies and procedures for specimen processing, and former § 493.1703 (now at §§ 493.1249(a) and (b)) requires the monitoring and assessment of these policies and procedures, and the implementation of corrective actions to resolve problems that are identified. These requirements ensure that the processing of mycobacterial specimens is monitored, assessed, and controlled, while allowing the laboratory to use any of several acceptable methods to do so.

We agree with ASM that, whenever possible, the frequency for control testing should be standardized for all microbiology subspecialties. Frequencies for individual reagents and stains are not specified in CLIA regulation for mycology and virology. For parasitology, a frequency requirement (to test once a month) is only given for permanent stains. The frequency requirement for all other reagents and stains in these subspecialties is the default contained in the general control procedure requirements that are now at § 493.1256(e)(1) and (2).

We agree appropriate requirements for molecular amplification procedures are needed, and that the NCCLS standards are an excellent reference for laboratories to use. Requirements addressing most of the recommendations made by ASM for amplification procedures are included in CLIA regulations, although not as specifically as suggested by this organization. CLIA regulations require the laboratory director to have control procedures to monitor the complete analytic process. For amplification procedures this includes, in general, validating cell lysis and ensuring absence of inhibitors, absence of contamination, and adequate amplification. The CLIA requirements for control procedures for all tests are now at § 493.1256(d). This provision requires all laboratories to follow manufacturer's instructions for control testing, and to, at minimum, conduct a test that includes two control materials of different concentrations (a positive and negative control are required for qualitative tests) on each day patient specimens are tested. CLIA regulations require that if the laboratory determines additional numbers or types of controls, or a greater frequency of running controls is needed to detect immediate error and monitor test performance over time, the numbers, types, and or frequency of controls must be increased accordingly.

While we agree with the recommendation made by ASM describing the positive and negative controls that should be used for molecular amplification procedures, the CLIA control requirements are minimum requirements and do not specify that a positive control must be at the low range of assay sensitivity, or that more than one negative control be tested daily. Likewise, these minimum requirements do not specify the types of controls that must be included with microbial genotyping, but only that two controls must be tested each day patient specimens are tested.

However, if test system instructions specify such control testing, or if the laboratory determines (during its initial evaluation of the test system at § 493.1253) that more controls are needed, the additional control testing must be performed.

For molecular amplification procedures, ASM also recommended the inclusion of an internal control in each run, primarily to detect inhibition of the amplification process. We agree that for some amplification procedures the presence of inhibitors or interfering substances in certain specimens may cause false negative test results, and that for these procedures, a control system is necessary to detect inhibition. However, as noted by NCCLS, inhibitors are not a significant source of false negative results for every test, and if inhibitors or interfering substances are encountered only rarely, NCCLS does not recommend running controls for inhibition. Therefore, we have added a requirement at § 493.1256(d)(3)(v) that states, if reaction inhibition is a significant source of false negative results, the laboratory must include a control system to detect such inhibition.

In response to the ASM recommendation that quantitative assays include two to three standards of known copy number, as stated above, under CLIA regulations, quantitative

tests must include at least two control materials of different concentrations per day. Standards may be used in lieu of control materials, as long as they are not the same as the materials used to calibrate the test system or establish a cutoff.

In reviewing the CLIA regulations concerning control procedures and QA requirements for molecular amplification procedures, the CLIAC discussed appropriate control procedures and QA for genetic testing (September 16, 1998 through September 17, 1998). CLIAC recommended that controls for genetic testing should be considered for laboratories in general, including ensuring that adequate controls are in place to minimize contamination. This is especially important when performing molecular amplification procedures. To ensure the control of contamination, we have amended the requirements for facilities, formerly at § 493.1204(a) (now at § 493.1101(a)) to require laboratories to be constructed, arranged, and maintained to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. A uni-directional workflow must be maintained for molecular amplification procedures not contained in closed systems. This must include physically separate areas for specimen preparation, amplification and product detection and, as applicable, reagent preparation. We believe these measures will decrease the potential for contamination to the extent possible in a clinical laboratory.

Comment: Several commenters requested clarification of the control requirements for kit systems used for bacterial and fungal identification. One commenter specifically requested the addition of a provision at § 493.1231, Mycology, that would require the testing of each new shipment of test kits or strips used for organism identification with organisms giving positive and negative reactions for each test before or concurrent with testing of clinical isolates. Another commenter questioned whether these systems would be subject to the requirement described at § 493.1202(c)(4) to test at least two levels of control materials each day of testing.

Response: We agree with the commenter that in mycology, or any other subspecialty area of microbiology, new shipments of test kits or strips used for organism identification should be tested with organisms giving positive and negative reactions for each test before or concurrent with initial testing of clinical isolates. This includes identification kits or panels that are inoculated and read manually, and those that are part of an automated instrument system. We are retaining the requirement formerly at § 493.1218(f)(1) (now at § 493.1256(e)(1)) that laboratories check each batch (prepared in-house), lot number (commercially prepared), shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates and/or reagents) when prepared or opened for positive and negative reactivity. We do not believe additional testing of these systems is needed if they are stored and maintained under appropriate conditions. Further testing is only necessary if labile reagents must be prepared or used each time the kit is used or if specified by the manufacturer.

Comment: Several commenters requested clarification of the control requirement at § 493.1218(b)(1) for qualitative tests as applied to microbiology procedures. The commenters asked which of the biochemical tests or media used for microbial identification would be considered qualitative tests.

Response: Biochemical tests using specific reagents or growth tests that employ selective or differential media (for example, indole tests, citrate media) that are a part of the total system of identification from culture are not considered qualitative tests in microbiology. Therefore, we are retaining the requirement formerly at § 493.1218(f)(1) (now at § 493.1256(e)(1)) that states laboratories must check each new batch (prepared in-house), lot number (commercially prepared), and shipment when prepared or opened for positive, negative, and graded reactivity, if applicable. Specifically, former § 493.1218(f)(4) (now at § 493.1256(e)(1) and (4)) requires each batch of media to be checked before or concurrent with initial use for sterility, and its ability to support, select, or inhibit growth, as intended, and/or provide the appropriate biochemical response. The manufacturer's control checks of media may be used if the product insert specifies they meet the NCCLS standards for media control testing. These individual procedures do not require control checks with each run of patient specimens or further testing unless specified by the manufacturer or under specialty or subspecialty control requirements. Biochemical tests or media that provide microbial identification from a direct specimen or culture (for example, direct antigen tests for group A streptococcus, bacterial serotyping from culture) are considered qualitative microbiology tests and are graded for reactivity. We are retaining the control procedures requirements for qualitative test systems formerly at § 493.1218(b)(1) (now at § 493.1256(d)(3)(ii)).

Comment: One commenter recommended we add ''XV discs or strips'' to § 493.1227(a)(2) that requires testing both positive and negative control organisms each week of use, and delete § 493.1227(b) that requires testing the XV discs or strips with only a positive control organism each week of use.

Response: Testing of XV discs or strips was limited to only a positive control each week of use because there is no known available control to check negative reactivity for the group of organisms that this test identifies. We are deleting the specific QC requirements for testing X, V, and XV disks or strips. These disks or strips are now subject to the general control procedure requirements formerly at § 493.1218(f)(1) (now at § 493.1256(e)(1)) that include testing each new batch (prepared in-house), lot number (commercially prepared), and shipment when prepared or opened for positive and negative reactivity. Since there is no control available to check negative reactivity for XV disks or strips, the use of only a positive control for XV disks or strips will be deemed to meet the CLIA regulation as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

Comment: Several commenters recommended we change the control requirement for daily testing of antimicrobial susceptibility procedures to a weekly requirement, as specified by NCCLS. One commenter also suggested manufacturers develop control procedures consistent with NCCLS antimicrobial susceptibility testing standards whenever feasible.

Response: CLIA requires daily control checks for antimicrobial susceptibility testing, formerly at § 493.1227(c)(2) (now at § 493.1261(b)(1)) unless CMS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). In this case, the procedure providing equivalent quality testing is the NCCLS standard allowing the laboratory to perform weekly control testing of antimicrobial susceptibility procedures after establishing accuracy control limits through initial daily testing. The laboratory may continue performing weekly control testing provided the control results do not exceed the established limits.

Comment: One commenter requested clarification of the control requirements for antimicrobial susceptibility testing

with regard to the frequency of testing the disks, media, and overall procedure. The commenter felt that there is a contradiction between §§ 493.1227(c) and (c)(2) and that one of these statements should be deleted.

Response: In the former regulation, antimicrobial susceptibility testing requires that whenever a new batch of media or a new lot number and shipment of antimicrobial agents (disks) are put into use, the laboratory must verify that the media and agents perform within acceptable control parameters for testing. Following this initial verification that the test components (that is, media and antimicrobial agents) are working appropriately, the test procedure must be checked routinely with appropriate control strains to ensure that it is being performed accurately and all components of the procedure continue to work properly. This routine control procedure must be performed each day of patient testing or can be performed weekly. The weekly QC testing will be deemed to meet CLIA requirements, if performed as specified in the approved procedure providing equivalent quality testing in Appendix C of the State Operations Manual (CMS Pub. 7). The control organisms must be within established control limits before patient results can be reported.

Although we did not intend for the requirements at §§ 493.1227(c) and (c)(2) to appear contradictory, we are revising the language now at § 493.1261(b) for clarification of these requirements. In addition, we are making conforming changes to the language pertaining to the requirements for antimycobacterial and antifungal susceptibility testing for consistency and to be current with testing performed in these subspecialties. These requirements, formerly at §§ 493.1229(d) and 493.1231(d), are now at §§ 493.1262(b) and 493.1263(b).

Comment: A number of commenters stated the control requirements for identification procedures used in mycobacteriology at § 493.1229(a) should not selectively require positive and negative acid-fast control organisms to check the iron-uptake test each day of use while requiring only a positive acid-fast control for all other procedures. The commenters recommended that all identification procedures used in mycobacteriology be tested each day of use with an acid-fast organism that produces a positive result, and an acid-fast organism that produces a negative result.

Response: We agree with these commenters and because the incidence of infection caused by a variety of mycobacteria is increasing significantly, it is important for laboratories to accurately identify individual species within this genus. This results in increasing numbers and types of identification procedures being performed and it is critical that the accuracy of each of these tests be verified each day of use. This can best be ensured each day of use by including both an acid-fast control organism that produces a positive reaction and an acid-fast control organism that produces a negative reaction for each test. We are revising the requirement formerly at § 493.1229(a) (now at § 493.1262(a)) to reflect this change.

Comment: One commenter expressed concerns regarding the expense of testing controls and stated that the frequency for checking positive and negative reactivity of the BACTEC NAP test used to identify *M. tuberculosis* should be changed from each day of use to each week of use. This commenter suggested the requirement for testing a positive control each day of use could be satisfied by subculturing the growth from the BACTEC bottle to a solid media to detect appropriate colony and microscopic morphology.

Response: The control requirements were written to address test complexity and specialties or subspecialties of testing, not specific test systems or procedures. Test-specific CLIA regulations are only developed when tests are not adequately addressed in the general or specialty or subspecialty requirements. The commenter requested a change in CLIA regulation because of the expense of performing controls each time the BACTEC NAP test is set up. The alternative method that the commenter suggests for a positive control is not actually a control on the ability of the NAP test to inhibit growth of *M. tuberculosis,* but is a confirmatory test for the presence of this organism.

Although we agree with confirming results of the NAP test, it is not the same as using positive and negative control organisms to check the NAP vials for their ability to inhibit growth of *M. tuberculosis* and to allow growth of other mycobacteria. However, we understand the financial concerns associated with running positive and negative controls each day of use for this test. Since the test has a growth control included as part of each test, and the manufacturer indicates the media is stable and does not recommend testing positive and negative organisms as frequently as each day of use, we agree with the commenter that laboratories should only be required to check positive and negative control organisms each week of use. In addition, we are specifying this requirement as provided at § 493.1256 as an alternative procedure in Appendix C of the State Operations Manual (CMS Pub. 7).

Comment: One commenter stated positive and negative reactivity should be checked each day of use for all acid-fast staining procedures, rather than each week of use.

Response: We agree with the commenter that both fluorochrome and conventional acid-fast stains should be tested more frequently than each week of use and that both positive and negative control organisms should be tested. Nonpathogenic mycobacteria in water supplies have been found to contaminate buffers, rinse water, or other reagents, producing false positive staining results. Given the widespread use of acid-fast stains with the increasing incidence of mycobacterial disease, it is critical that the accuracy of these tests be verified each day of use. Therefore, we are deleting the requirements formerly at §§ 493.1229(b) through 493.1229(c) for testing fluorochrome and conventional acid-fast stains each week of use. The requirement for testing conventional acid-fast stains will now default to the general control requirement for stains formerly at § 493.1218(f)(2) (now at § 493.1256(e)(2)) that requires testing staining materials for intended reactivity each day of use. For stains that provide positive and negative reactivity (intended reactivity), we are revising the language to clarify that stains must be tested with positive and negative controls each day of use. By eliminating the subspecialty requirement for fluorochrome acid-fast stains, the general control requirement for fluorescent stains formerly at § 493.1218(f)(3) (now at § 493.1256(e)(3)) becomes applicable to these procedures. This general requirement specifies testing for positive and negative reactivity each time of use. It is appropriate to require the same control testing for fluorochrome acid-fast stains as are required for all other fluorescent stains.

Comment: One commenter recommended the deletion in bacteriology of testing positive and negative organisms each week of use for acid-fast stains as required in § 493.1227(a)(2) and replacement of the mycology term ''acid-fast stain'' at § 493.1231(c), with ''modified acid-fast stain.'' This commenter emphasized that acid-fast stains are used in mycobacteriology rather than bacteriology, and that the procedure for staining used in mycology is a modification of the acid-fast stains performed in mycobacteriology.

Response: We agree with this commenter on both of these points. Although acid-fast stains are occasionally performed in bacteriology, by deleting the requirement in bacteriology for testing acid-fast stains each week of use, it defaults to the general requirement formerly at § 493.1218(f)(2) (now at § 493.1256(e)(2)) that requires laboratories to test staining materials for their intended reactivity (including positive and negative reactivity, as appropriate) each day of use. We agree with the commenter that the staining procedure in mycology is a modification of acid-fast stain used in mycobacteriology; therefore, we are deleting the requirement formerly at § 493.1231(c) for performing control testing each week of use for (modified) acid-fast stains. Again, this results in the control requirement for these stains defaulting to the general requirement for testing each day of use and is reasonable based on the fact that we are now requiring positive and negative controls for all acid-fast stains each day of use.

Comment: One commenter stated that the control regulation for mycology and mycobacteriology should require the use of a safety cabinet when testing in these specialty areas.

Response: We agree with the commenter that safety is an important factor in laboratory testing, formerly at § 493.1204(b) (now at § 493.1101(d)) and laboratories are required to maintain a safe testing environment. Safety precautions must be established and observed to ensure protection from biohazardous materials. Under §§ 493.1445(e)(2) and 493.1407(e)(2), the laboratory director is responsible for ensuring a safe environment is provided for employees conducting non-waived testing. In addition, other government agencies enforce State and local laws and other Federal standards that ensure protection of employees and the public from biohazardous materials. These agencies include the Occupational Safety and Health Administration and the Environmental Protection Agency.

Comment: One commenter stated that the wording at § 493.1235(c) is inappropriate. The commenter recommended the replacement of the word ''culture'' (referring to uninoculated controls) with ''incubate'' or ''hold.'' This individual stated that the use of the term culture as specified at § 493.1235(c) generally means to inoculate and inspect for growth.

Response: We agree with this commenter and are replacing the term ''culture'' with the term ''incubate'' formerly at § 493.1235(c) (now at § 493.1265).

Comment: A commenter requested clarification of the control requirements for virology as they pertain to direct antigen detection. This commenter recommended the addition of a statement to § 493.1235 following paragraph (c) that would read ''The above QC requirements are not applicable to virology testing performed using direct antigen detection methods.''

Response: We agree with the commenter that the wording formerly at § 493.1235(c) needs clarification. There are several types of tests that identify viruses, but this requirement only applies to cell culture methodologies used to isolate and identify viruses. Therefore, we are changing the language for this requirement, now at § 493.1265(a), to make it specific to cell culture methodologies.

Sections 493.1237 Condition: Diagnostic Immunology; 493.1239 Condition: Syphilis Serology; and 493.1241 Condition: General Immunology

Specific comments received and response to comments regarding §§ 493.1237, 493.1239, and 493.1241 are set forth below.

Comment: A commenter stated § 493.1239(e) and § 493.1241(d), which refer to facilities manufacturing blood and blood products, should be deleted. This individual believes CLIA regulations should not cover manufacturing requirements.

Response: We disagree with the commenter. These requirements refer to testing requirements under CLIA regulations (donor specimens) regardless of where the testing is performed. However, we are moving these requirements, formerly under the subspecialties of syphilis serology and general immunology, and placing them with other requirements addressing the immunohematological collection, processing, dating, labeling, testing, and distribution of blood and blood products now at § 493.1271, Immunohematology (formerly at § 493.1273(a)).

Comment: One commenter requested clarification of the QC requirements for serological testing (both syphilis serology and general immunology) to run patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, and a negative control. Specifically, this commenter questioned if these requirements refer to the additional controls run on a new kit to verify reproducibility, or if they pertain to the daily testing of the positive controls supplied in commercial kits. Other commenters objected to including two control materials each time patient testing is performed. One commenter thought only a positive control was necessary for immunology tests if the patient results were negative.

Response: We agree with the commenters who objected to the syphilis serology and routine immunology requirements requiring two control materials each time patient testing is performed. With the development of more accurate and stable test systems, the requirements formerly at § 493.1239(b) and § 493.1241(a) for assaying controls concurrently with patient specimens are excessive for many of the test systems. We are, therefore, deleting these requirements. Laboratories performing these tests will now need to meet the applicable control procedures at § 493.1256. In addition, the laboratory must meet the requirements that pertain to establishing or verifying a test system's performance specifications before putting a new test system into routine use formerly at § 493.1213 (now at § 493.1253).

We disagree with the comment that testing only a positive control is sufficient if the patient results are negative. Laboratories, at a minimum, must follow the manufacturer's instructions and for qualitative tests, assay a positive and negative control each day of patient testing (now at § 493.1256(d)(3)(ii)). For procedures producing graded or titered results, a control material with graded or titered reactivity, as applicable, and a negative control material must be assayed each day testing is performed formerly at §§ 493.1239(b) and 493.1241(a) (now at § 493.1256(d)(3)(iii)). The control material supplied in commercial kits (test systems) may be used to meet the requirements formerly at §§ 493.1239(b) and 493.1241(a) (now at § 493.1256(d)(3)(iii)) providing the material is of known reactivity (titered or graded, as applicable) and is not the same material used to establish a cutoff or calibrate the test system if calibration of the test system is required (now at 493.1256(d)(9)).

Section 493.1245 Condition: Routine Chemistry

Specific comments received and response to comments regarding § 493.1245 are set forth below.

Comment: One commenter expressed concern that §§ 493.1245(c) and (d) could be interpreted to mean that the same material could be used to calibrate the instrument and verify or control the test run for blood gas analyzers. The commenter stated that this would not

detect problems arising from deteriorated or contaminated calibrating solutions. The commenter also recommended the reference to calibrators be deleted from these sections and that control testing be performed using only control material.

Response: We agree with this commenter. It was never our intent to infer by the wording of these requirements that calibration material used to calibrate a test system could be used as a control to monitor the test system's performance. However, we allow the use of calibration material as a control material provided it is from a different lot number than that used to calibrate the test system or establish a cut-off. Therefore, we are clarifying the use of calibration materials as control materials (now at § 493.1256(d)(9)), and eliminating the terms ''calibration'' and ''calibration material'' from the blood gas analysis requirements (now at § 493.1267).

Comment: One commenter stated testing one sample of blood gas control per 8 hours of patient testing is not sufficient and is inconsistent with the general requirement for quantitative tests at § 493.1218(b)(2) that requires two controls of different concentrations with each run of patient specimens. This commenter recommended that at least two levels of control be required every 8 hour shift.

Response: We revised the general control requirement formerly at § 493.1218(b) (now at § 493.1256(d)). The requirement now specifies, at a minimum, assaying two levels of control materials each day patient specimens are tested. We are deleting the term ''run'' from the regulation. Also, laboratories must perform control testing using the number and frequency specified by the manufacturer or established by the laboratory when those frequencies meet or exceed the minimum requirement. Therefore, the minimum control requirement for quantitative tests, unless a more frequent interval is recommended by the test system's manufacturer or the laboratory, is two control materials of different concentrations each day patient specimens are tested.

The requirement for one control material per 8 hours for blood gas analyses, formerly at § 493.1245 (now at § 493.1267) exceeds these general QC requirements. The blood gas control requirements also require the laboratory to use a combination of control materials that check low and high values each day of testing. In addition, for blood gas instruments that do not internally verify calibration at least every 30 minutes, the laboratory must include one sample of control material each time patient samples are tested. This final rule provides minimum requirements. Based on the laboratory's verification of the test system's performance specifications before routine patient use (now at § 493.1253) and establishment of its control procedures (now at § 493.1256(d)), the laboratory may determine that it needs to run additional control materials or run control materials at a more frequent interval to assure accurate and reliable test results.

Section 493.1249 Condition: Toxicology

Specific comments received and response to comments regarding § 493.1249 are set forth below.

Comment: One commenter asked that the term ''drug abuse screening using thin layer chromatography'' at § 493.1249, Toxicology be modified to read ''drugs-of-abuse screening using thin layer chromatography'' (''drugs-of-abuse'' is defined by the National Institute for Drugs of Abuse now National Substance Abuse and Mental Services Health Administration Laboratory Certification Program). This commenter also requested deletion of the requirement under § 493.1249(b) for at least one control sample to be processed and included in each chamber, stating that all environmental, chemical and material variables within a chamber are visualized by running calibration materials. The commenter added that controls should be analyzed with each run, and that each run should not exceed a 24 hour period.

Response: We agree with the commenter that the control requirements formerly at § 493.1249 are not clear; therefore, we are revising the language to clarify the requirements. We are moving the requirements for thin layer chromatography to § 493.1256(d)(4) under Control procedures. In addition, we are revising the term ''drug abuse screening'' to read ''all known substances or drug groups'' identified and reported by the laboratory, to accommodate the wider use of the technology. However, we disagree with the commenter's statement that analyzing one control material per 24 hours is sufficient. If extractions and tests are performed more frequently than once per 24 hours, each ''plate'' or ''card'' (formerly referred to as ''chamber'') must be spotted with at least one sample of control material to ensure that appropriate separation, and as applicable, extraction took place. The inclusion of a calibration material containing all known substances or drug groups reported by the laboratory using thin layer chromatography on each plate or card ensures appropriate identification of the substances or drugs in patient specimens.

Section 493.1253 Condition: Hematology

Specific comments received and response to comments regarding § 493.1253 are set forth below.

Comment: We received several comments requesting the deletion of QC requirements in hematology because they would increase laboratory costs.

Response: We agree with the commenters that the requirement to include two levels of control material each 8 hours of testing for automated hematology analyzers (for example, cell counters and differential counters) is somewhat excessive in light of the proven stability and reliability of these instruments. Therefore, we are deleting the specialty-specific control requirement for automated hematology analyzers formerly at § 493.1253(b), and are requiring laboratories to meet the general control requirements (now at § 493.1256(d)) when using automated hematology analyzers. However, the manufacturer's instructions and the laboratory's evaluation of the instruments' stability, environmental effects, and operator variance will determine the actual number, type, and frequency of testing control materials. At a minimum, the laboratories will have to test two control materials of different concentrations each day.

Comment: One commenter requested that we remove the requirement for duplicative testing of patient and control specimens for manual coagulation tests, as required at § 493.1253(d)(2), since proficiency testing requirements do not allow for duplicative testing.

Response: We disagree with the commenter and are retaining the requirement for duplicative testing of patient specimens and control materials for manual coagulation testing (now at § 493.1269(c)(2)). CLIA regulations for proficiency testing (PT) (§ 493.801(b)(2)) require the laboratory to test PT samples the same number of times that it routinely tests patients' samples. Therefore, since patient specimens must be routinely tested in duplicate, PT samples for manual coagulation testing must also be tested in duplicate.

Section 493.1257 Condition: Cytology and Section 493.1259 Condition: Histopathology

Approximately 66 percent of the 1,030 comments received concerning the final rule with comment period,

subpart K, were in response to the cytology requirements. The comments were primarily from professional organizations, cytotechnologists, pathologists, and other physicians. The major issues that commenters addressed include—

(1) Workload limits; (2) review of reactive reparative cases by a technical supervisor; (3) the 10 percent rescreen of negative cases screened by a cytotechnologist; and (4) the 5-year retrospective review of negative smears from patients with a current high grade lesion.

Specific comments and response to comments regarding §§ 493.1257 and 493.1259 are set forth below.

Comment: Several commenters stated the language ''non automated microscopic technique'' used to describe the slides that are counted in the workload limit is inappropriate and might be confused with slides that are screened using a motorized mechanical stage or with slides that are read by an automated instrument.

Response: We agree with the commenters and are removing the wording ''non automated microscopic technique.'' We also want to emphasize that slides that are read with a human component must be included in the 100 slide limit; slides that are read by an automated instrument that do not require human review are not included in the workload limit.

Comment: A number of commenters and one cytology organization were opposed to establishing the workload limit at 100 slides examined in a 24 hour period. A few commenters felt the workload limit was too restrictive, while other commenters and the cytology organization indicated the limit was too high.

Response: The CLIA statute at section 353(f)(4)(B)(i) specifically states that the standards must establish ''the maximum number of cytology slides that any individual may screen in a 24 hour period.'' Limiting the number of slides that may be examined in 24 hours to no more than 100 is the absolute maximum workload limit for an individual. However, we agree with the commenters that this may not be an appropriate workload for all individuals. To clarify our position, formerly at § 493.1257(b)(1) (now at § 493.1274(d)(2)), we specify that the Federal workload limit was not to be used as a performance target for cytology personnel. In addition, we specified formerly at § 493.1257(c)(4) (now at § 493.1274(d)(1)) that the cytology technical supervisor must establish a workload limit (not to exceed 100 slides examined per 24 hours) for each person examining slides and that at least every 6 months, the technical supervisor must re-evaluate and adjust, if necessary, each individual's workload limit. In addition, we are emphasizing that the workload limit applies only to individuals and does not apply to automated slide examination systems that may be used to screen slides and identify those smears requiring no human microscopic examination.

Comment: One organization asked whether the workload requirements are applicable to technical supervisors or only to cytotechnologists. Several commenters suggested the workload requirement only applies to cytotechnologists.

Response: The workload requirements apply to any individual who performs primary screening of cytology slides. This may be a technical supervisor or a cytotechnologist. We are also clarifying that while tissue pathology slides and previously examined gynecologic and nongynecologic slides are not included in the 100-slide workload limit for technical supervisors, the technical supervisor must subtract the time spent evaluating these slides and the time spent on any nonscreening duties from the time spent screening slides to appropriately adjust the workload.

Comment: Many commenters and the cytology professional organizations opposed the workload provision to count as one-half slide those smears made using automated, semiautomated, or other liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the slide. Some commenters indicated that this workload limit should apply only to nongynecologic preparations, while others thought it premature to use this calculation for any cytologic preparations until sufficient scientific studies have been completed to document the establishment of a workload limit appropriate for these preparatory techniques.

Response: In order to address concerns of the commenters, we are making several clarifications. First, the 200-slide workload limit was initially established in the February 28, 1992 final rule with comment period published in the **Federal Register** (57 FR 7002) in response to innovations in cytology preparatory techniques and acknowledgment that slide preparations that only occupy a portion of the slide will not count as a whole slide. Slide preparations (gynecologic and nongynecologic) made using automated, semi-automated, or other liquid-based preparatory techniques that result in a specimen that only occupies a small portion of the slide, are counted as one-half slide. Second, on January 19, 1993, we published a final rule with comment period in the **Federal Register** (57 FR 5212) removing gynecologic preparations. On July 22, 1993, we published a technical correction notice in the **Federal Register** (58 FR 39154) that inadvertently reinserted gynecologic preparations. In addition, Cytyc, manufacturer of ThinPrep ™, agrees that a 200-slide workload limit is too high for gynecologic preparations and has requested that the 200 slide workload limit not be applicable to gynecologic slides. We agree with the commenters and Cytyc corporation, and we are eliminating gynecologic slides from the 200-slide workload limit (now at § 493.1274(d)(2)(iii)). The 200-slide workload limit will only apply to nongynecologic slides.

Comment: Many Commenters and the Cytology organizations agreed that a workload limit was appropriate for gynecologic preparations. However, they were opposed to establishing a workload limit for nongynecologic smears because these preparations vary greatly in specimen type or source, preparatory techniques, and cellularity requiring various time frames for evaluation. The commenters acknowledged the difficulty in establishing a workload limit for individuals who examine nongynecologic preparations exclusively or a combination of gynecologic and nongynecologic smears. For fine needle aspirations, several organizations suggested using the methodology employed by New York State to prorate nongynecologic preparations, that is, for cases involving one to three slides, each slide is counted as one and for cases having four or more slides, a maximum of three slides are counted for workload purposes.

Response: We agree with the commenters that it is easier to establish a workload limit for gynecologic smears than for nongynecologic preparations because of the variability in nongynecologic preparations; however, the statute requires us to determine the maximum number of cytology slides that an individual can screen in a 24-hour period. Therefore, the workload limit is applicable to all cytology slides, including gynecologic and nongynecologic preparations. Concerning the New York State proration of nongynecologic slides, this practice is no longer in use in New York.

Comment: Several individuals asked for clarification on the specific guidelines that a technical supervisor should use to determine the maximum workload for an individual. Some

commenters noted the technical supervisor may have to justify a workload that is lower than 100 slides to hospital and laboratory administrators.

Response: Formerly at § 493.1257(c)(4)(i), individual workload is based on the performance evaluation described formerly at § 493.1257(c)(3). Therefore, we are revising the requirement, now at § 493.1274(d)(1)(i), to make it more understandable. Performance must be evaluated using the following: (1) Re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists; and (2) comparing the cytotechnologist's interpretation with the final diagnosis on cases of atypical squamous cells of undetermined significance (ASC–US), low-grade squamous intraepithelial lesion(LSIL), high-grade squamous intraepithelial lesion (HSIL), glandular epithelial cell abnormalities, or other malignant neoplasms. However, the evaluations listed in the former CLIA regulations must be viewed as minimal requirements and the laboratory may have additional mechanisms or criteria to evaluate individual performance. For example, the following provisions in the CLIA regulations may be used: (1) Number of discrepant findings on the retrospective review of previous negative cases from patients with a current HSIL, adenocarcinoma or other malignant neoplasm; (2) individual statistics evaluated against the laboratory's overall statistics; and (3) competency assessment activities.

Comment: Many of the commenters and the cytology organizations suggested that the requirement for confirmation of cases by the technical supervisor be limited to those having atypical squamous or glandular cells, or any premaligment or malignant cell changes. The commenters suggested deleting the reference requiring confirmation of ''reactive or reparative changes,'' stating that the requirement was excessive. Other commenters recommended changes to allow technical supervisors the discretion to determine the level of supervisions, that is, review of cases with benign cellular changes, needed by each employee. In addition, several commenters suggested we revise the language to include the Bethesda terminology.

Response: We have not removed all reference to reactive and reparative changes because many laboratories still use this classification. The regulation, however, incorporates the Bethesda terminology, which provides for a uniform categorization of the cellular changes seen in gynecologic cytology. Most of the slides formerly classified as having ''reactive and reparative'' changes that would have exhibited marked or extensive cellular changes on technical review will, therefore, be classified as ASC–US or as having a squamous cell abnormality under the Bethesda terminology. As specified at § 493.1274(e), all of these slides are required to be reviewed by the technical supervisor. However, we have retained the classification reactive and ''reparative changes,'' and similar cellular changes under the Bethesda category ''Negative for Intraepithelial Lesion or Malignancy'' that would formerly have been categorized as reactive or reparative to encompass those slides needing review by the technical supervisor. Technical supervisors continue to have the discretion to review more cases as necessary to train and manage cytotechnologists under their supervision. Although we are not requiring the use of the Bethesda terminology, the majority of the laboratories have adopted it, and we encourage other to do the same.

Comment: One organization stated that the technical supervisor's signature on the worksheet is acceptable documentation for the review of abnormal gynecologic cases. For nongynecologic cases, the organization suggested that laboratories allow the technical personnel to verify the final computer generated report that would include the name of the technical supervisor who reviewed the case. Another commenter asked for clarification on electronic signatures and whether CLIA regulations allow electronic requisitions.

Response: We do not believe that any change in the CLIA regulations is appropriate. The final report must be verified by the technical supervisor who reviewed the case and signs the report, and electronic signatures must be authorized and verified by the technical supervisor who signs the report. As specified at § 493.1241, electronic requisitions are acceptable, as long as the requisition contains the required information.

Comment: Several commenters, including one cytology organization, disagreed with requiring laboratories to rescreen 10 percent of the cases interpreted to be normal or negative by cytotechnologists. One organization stated the 10 percent rescreen is a statistically invalid mechanism for reducing the false negative rate and suggested the requirement be replaced by a goal-oriented statistically valid system for promoting laboratory QC. One organization was opposed to requiring laboratories to complete the 10 percent rescreen before reporting patient results.

Response: The CLIA statute requires ''* * * random rescreening of cytology specimens determined to be in the benign category * * *'' Accordingly, random rescreening of negative cases is required in CLIA rules. We view the 10 percent rescreen as a minimum requirement and only one component of the laboratory's control procedures and QA activities. In addition, rescreening is supported by the results of cytology surveys conducted under CMS contract that includes rescreening approximately 0.1 percent of the laboratory's caseload. In many of these surveys, diagnostic discrepancies were noted between the contractor's evaluation of patient specimens and the results reported by the laboratory, even though the sample rescreened was less than 10 percent of the laboratory's caseload. The control procedures, including the 10 percent rescreen, assess the quality of the laboratory's results, and the rescreen must be completed before issuing patient reports on the slides selected for the 10 percent rescreen as specified formerly at § 493.1257(d)(1)(iii) (now at § 493.1274(c)(1)(ii)).

Comment: One commenter asked whether the 10 percent re-evaluation of negative cases could be performed by the same individual who performed the primary review.

Response: The 10 percent rescreen of negative cases is one provision of the cytology control procedures specified formerly at § 493.1257(d) requiring laboratories to have a program designed to detect errors in cytology examinations. This provision is now at § 493.1274(c). Ten percent of the cases interpreted as negative by cytotechnologists must be reevaluated by a cytology technical supervisor qualified under §§ 493.1449(b) or 493.1449(k), a cytology general supervisor qualified under § 493.1469(b)(2), or a cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2). For laboratories with a solo pathologist (no cytotechnologists), the 10 percent rescreen need not be performed; however, the following cytology QC procedures must be performed: a laboratory comparison of clinical information and histopathology reports (as specified at § 493.1274(c)(2)), a retrospective rescreen of normal and negative cases received within the previous 5 years from a patient with a current high grade lesion (as specified at § 493.1274(c)(3)) and annual statistical evaluation (as specified at § 493.1274(c)(5)).

Comment: Many cytology organizations disagreed with requiring review of all normal or negative slides from the previous 5 years for any patient having a current high grade intraepithelial lesion or above. The commenters felt that the 5-year review was unreasonable and unnecessarily burdensome and suggested that the review include only the two most recent smears, if available in the laboratory. A number of commenters noted the error at § 493.1257(d)(3) in referring to patients with ''a current high grade or above intraepithelial lesion . . .'' and suggested rewording the requirement for retrospective review of negative cases from patients having a ''current high grade intraepithelial lesion or cancer.''

Response: We are not reducing the requirement for review of negative cases from the previous 5 years for patients having a current high grade intraepithelial lesion or cancer because the law requires ''. . . for each abnormal cytological result, rescreening of *all* (emphasis added) prior cytological specimens for the patient, if available.'' However, we appreciate and agree with the commenters' suggestion about rewording the requirement, formerly at § 493.1257(d)(3) (now at § 493.1274(c)(3)) to reflect current terminology.

Comment: One organization asked for clarification on the time frame for completion of the retrospective review of cases with a current high grade lesion or above and the histology and cytology correlation.

Response: The retrospective review and the histology and cytology correlation are part of the control procedures and must be completed in a timely manner. Since there is a possibility that this QC activity could result in the issuance of a corrected report that may affect patient treatment, the laboratory must have procedures in place that include time frames for these activities.

Comment: Several commenters and cytology organizations disagreed with requiring laboratories to compare the case reviews of each individual with the laboratory's overall statistical values. The commenters stated that the case mix (specimens from various clinics with different patient populations) varies and these statistics should not be used to assess individual performance. In smaller laboratories the statistical comparison may not be valid due to the small numbers. It was suggested that laboratories be given flexibility to determine the best approach for implementing the control procedure requirements and evaluating individual performance.

Response: We established these requirements as a result of comments provided in response to the proposed rule that was published on May 21, 1990 in the **Federal Register** (55 FR 20896). The commenters stated that reviewing the laboratory's data provided useful information on overall laboratory practice as well as individual performance. We believe these requirements have provided valuable information for assessment of laboratory and individual performance; therefore, we are not making any revisions. However, laboratories may document situations that affect the laboratory's statistics and individual case reviews.

Comment: One cytology organization was opposed to requiring laboratories to document cases for which histologic reports were unavailable for comparison with abnormal gynecologic results, stating that it was time consuming and burdensome and provided no benefit to the patient.

Response: In an attempt to minimize the burden, (now at § 493.1274(c)(5)(iv)), we are requiring documentation of only the number of cases that have histology correlation. We believe this information is necessary to determine the laboratory's success in obtaining histology reports for the histology and cytology correlation.

Section 493.1259 Condition: Histopathology

Specific comments received and response to comments regarding § 493.1259 are set forth below.

Comment: Two medical professional organizations disagreed with the requirements at § 493.1259(c) that precluded neurologists from examining nerve and muscle biopsies. Also, in May 1993, CLIAC recommended that neurologists with specialized training and board certification qualify as technical supervisors, general supervisors, and testing personnel of neuromuscular histology. Without recognition of this training, neurologists would be required to refer neuromuscular tissue specimens to an anatomic pathologists for examination.

Response: We are amending the histopathology QC requirements formerly at § 493.1259(c) (now at § 493.1273(c)) to allow individuals who have successfully completed a training program approved by HHS to examine and provide reports for neuromuscular pathology. In Appendix C of the State Operations Manual (CMS Pub. 7), subpart K, we will specify that the training program developed by the American Academy of Neurology Committee for Neuromuscular Pathology is approved by HHS. We are making the change to § 493.1273 rather than the personnel requirements in subpart M, because in this final rule, we are limiting the personnel revisions to the phase-in provisions addressed in the December 28, 2001 proposed rule. HHS received numerous personnel comments in response to the February 28, 1992 final rule with comment period which we intend to address in a future regulation.

Section 493.1265 Condition: Histocompatibility

Specific comments received and response to comments regarding § 493.1265 are set forth below.

Comment: Several commenters were pleased with the final CLIA rule for histocompatibility testing and felt the majority of the concerns raised over the proposed rule had been addressed. They noted the requirements now generally reflect the state of the art laboratory practices in this specialty area of testing that is continuing to evolve.

Response: We appreciate this acknowledgment of the efforts made in developing the histocompability QC requirements specified in the final rule with comment period that was published on February 28, 1992 in the **Federal Register** (57 FR 7170). In our continuing endeavor to represent current technology and practice, we are updating some of the terminology and references used in this section. We are also deleting several requirements that are duplicative of requirements found elsewhere in the CLIA regulation. In addition, we are adding clarifying language and reorganizing the requirements in this section that apply to HLA typing, disease associated studies, antibody screening, crossmatching, transplantation, and general requirements that apply to every histocompatibility laboratory regardless of the testing and services offered by the laboratory.

Comment: One commenter requested the requirements for histocompatibility testing be separated into three groups: solid organ transplantation, including renal; bone marrow transplantation; and histocompatibility testing for transfusion services.

Response: We acknowledge that the organization of the histocompatibility requirements found in the final rule with comment period may have caused some confusion to the reader trying to determine what testing requirements apply to each type of organ or tissue transplant. While there are various ways to group the requirements in this specialty, we are reorganizing this section by first delineating the general requirements for histocompatibility

testing (now at § 493.1278(a)) and specifying the requirements for HLA typing (now at § 493.1278(b)), disease associated studies (now at § 493.1278(c)), antibody screening (now at § 493.1278(d)), crossmatching (now at § 493.1278(e)) and transplantation (now at § 493.1278(f)). In addition, we believe this reorganization, along with other revisions, will greatly enhance the readability of this section and clarify the requirements that must be met for each type and level of histocompatibility testing performed by the laboratory.

Comment: One commenter pointed out the requirement at § 493.1265(a)(4) that addresses reagent typing sera inventories prepared in-house should also require that the specificity of the reagent be indicated. The commenter also requested clarification of the term ''typing tray'' used at § 493.1265(a)(9)(i) since the term can refer to any 96, 72, or 60 well microtiter tray used in the HLA laboratory. The commenter stated that without clarification, it is unclear whether the control requirements specified at this requirement refer only to trays used for HLA typing or if they include trays run in an attempt to identify the presence of circulating HLA antibodies.

Response: We agree that reagent specificity must be indicated on the laboratory's in-house prepared reagent typing sera inventory and are amending the requirement now at § 493.1278(a)(3) accordingly.

The commenter is correct to question the scope of the requirement formerly at § 493.1265(a)(9)(i) that addressed control requirements for typing trays. In addition, the term ''typing tray'' is somewhat restrictive in that testing performed with newer and emerging technologies may not necessarily use microtiter trays. Therefore, we are revising the requirement for clarification, and, with the reorganization of this section, § 493.1278(b)(6) now describes the controls a laboratory must use for each HLA typing, and § 493.1278(d)(6) addresses the controls a laboratory must use when performing antibody screening.

Comment: One commenter requested that the CLIA regulations mandate HLA antibody identification when panel screening studies indicate the presence of a lymphocyte-reactive antibody. In addition, the laboratory should determine if this is an autoantibody or alloantibody. The commenter also requested the CLIA rule require that the specific technique used in HLA antibody screening be at least as sensitive as the complement-dependent lymphocytotoxicity technique used in the final donor crossmatch.

Response: Histocompatibility testing is a rapidly evolving, highly complex specialty. Its role in predicting long-term allograft survival is the subject of numerous research studies. Not all antibody reactions have a defined specificity, and the clinical relevancy of each antibody has not been established. Mandatory antibody identification may be impractical, if not impossible, and uninformative in these cases. However, we agree that antibody identification must be performed when appropriate to support clinical transplant protocols and § 493.1445(e)(3)(i) requires the laboratory director to select test methods that are capable of providing the quality of results required for patient care. It is the laboratory director's responsibility to institute more stringent testing protocols as necessary for quality patient care. Therefore, we are adding a requirement at § 493.1278(d)(7) for laboratories that perform antibody identification to have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

We agree with the commenter that the laboratory must use a technique that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay. In addition, to detect antibodies to HLA Class II antigens, the laboratory must use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens. We are adding these two new requirements at §§ 493.1278(d)(1) and 493.1278(d)(2).

To ensure quality laboratory practices and for consistency with the two new requirements, we are specifying that techniques used for crossmatching must be documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay (now at § 493.1278(e)(1)). In addition, when performing HLA typing, the laboratory must use a technique that is established to optimally define, as applicable, HLA Class I and II specificities (now at § 493.1278(b)(1)).

Comment: A number of commenters were opposed to the elimination of mandatory monthly screening for HLA antibodies, since most, if not all, laboratories lack access to accurate information regarding each potential transplant recipient's exposure to sensitizing events. This is compounded by the probability that not all potentially sensitizing events have been identified. A few commenters acknowledged that the cost of monthly screening can be prohibitive and suggested there may be some instances when monthly screening may not be necessary. However, most commenters agreed that studies need to be done to determine the optimum frequency of antibody screening.

Response: We agree with the commenters and recognize the importance of developing an accurate immunological history of the potential transplant recipient and the difficulty of identifying and obtaining information on all potential sensitizing events. We also appreciate the efforts to control healthcare costs by eliminating unnecessary and or redundant testing. To provide flexibility and allow responsiveness to emerging research data and information, we are revising the requirements formerly at §§ 493.1265(a)(2)(ii) and (a)(8)(i) (now at §§ 493.1278(d)(4) and (d)(5)) to require the laboratory to make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch. In this regard, the laboratory must have available and follow a policy, consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

Comment: Three commenters noted that DNA typing involves the genes rather than the expressed antigens; therefore, § 493.1265(a)(10) would be more accurate if changed to read, ''Compatibility testing for HLA class II polymorphisms should utilize techniques, for example, mixed lymphocyte culture, homozygous typing cells, or DNA analysis.''

Response: We agree with the commenters that the wording of the requirement formerly at § 493.1265(a)(10) is somewhat inaccurate and also believe that the requirement may be too restrictive for future methodologies, technologies, and transplantation protocols. Therefore, we are deleting this requirement for the laboratory to use specific techniques, for example, mixed lymphocyte cultures, to determine HLA Class II incompatibilities.

Comment: One commenter stated that the requirement at § 493.1265(a)(13) to have histocompatibility testing personnel evaluate unknowns on a monthly basis is excessive and should be reduced to once every 6 months.

Response: Histocompatibility testing is a highly complex specialty with great potential for harm to the patient if the testing is incorrectly performed. CLIA regulations specify formerly at

§ 493.1445(e)(13) that the director has to ensure that policies and procedures are established for monitoring employee competency and to identify needs for remedial training or continuing education. Monitoring employee competency may include the evaluation of previously tested specimens as unknowns. However, we are deleting this former requirement at § 493.1265(a)(13) because we believe it is somewhat duplicative of the laboratory director responsibility.

Comment: Three commenters, including a professional organization, recommended that living transplants be deleted from § 493.1265(b)(2) that requires the performance of mixed lymphocyte cultures or other augmented testing to evaluate HLA class II compatibility. The commenters stated that although appropriate for bone marrow transplantation, mixed lymphocyte culture is performed rarely in living-related kidney transplantation where HLA Class II compatibility and genetic linkages can be adequately determined using serological methods. In addition, the commenters maintained that mixed lymphocyte culture tests were unnecessary in solid organ transplants and not considered a contraindication to this type of transplantation.

Response: We agree with the commenters. The phrase, ''and living transplants,'' formerly at § 493.1265(b)(2), was deleted in a technical correction notice published on January 19, 1993. In addition, we recognize the evolving nature of transplant medicine makes it difficult to prescribe standards for testing protocols that may be quickly outdated with emerging research data and information, for example, graft survival, acute, and chronic rejection. For this reason we are revising the requirements formerly at §§ 493.1265(b) and (c) that specified the type of testing to be performed for each transplant type. We are requiring (now at § 493.1278(f)(1)) that laboratories performing histocompatibility testing for transfusion and transplantation purposes have available, and follow, written policies and protocols specifying the histocompatibility testing to be performed for each type of cell, tissue, or organ to be transfused or transplanted. The laboratory's policies must address, as applicable, testing protocols for cadaver donor, living, living-related and combined organ and tissue transplants; the level of testing required to support clinical transplant protocols (for example, HLA typing at the antigen or allele level); and any additional testing required for patients at high risk for allograft rejection. In addition, we believe this less prescriptive, but laboratory-specific requirement provides the flexibility required to ensure laboratory practice that is responsive to advances in transplantation medicine and laboratory methodologies and technology.

Comment: One commenter stated that the requirement, at § 493.1265(b)(3), to provide the results of the final crossmatch before nonrenal solid organ transplantation when the recipient has demonstrated presensitization is not necessarily relevant or realistic for all types of grafts. The commenter cited the short viability time of certain organs (heart and lung) and unpublished data pertaining to the nonrelationship between high-titered positive donor T cell crossmatches and liver allograft survival.

Response: We agree with the commenter that the period of time that organs, for example, the liver, pancreas, and heart remain viable after removal from the donor is often not sufficient for the laboratory to complete the crossmatch. The regulation formerly at § 493.1265(b)(3) (now at § 493.1278(f)(3)) has been revised to require laboratories to develop and follow policies for testing and providing results of final crossmatches when the recipient has demonstrated presensitization by prior serum screening. In addition, the policy must address emergency transplant situations that would not allow time for the laboratory to perform prospective crossmatches. In addition, we would like to clarify that the intent of § 493.1278(f)(3) is not to preclude the use of crossmatch-positive nonrenal organs and tissues but to ensure, whenever possible, the availability of all pertinent test results on which the physician(s) may base their decision to proceed with the transplant.

Section 493.1267 Condition: Clinical Cytogenetics

Specific comments received and response to comments regarding § 493.1267 are set forth below.

Comment: One commenter suggested the cross-references to subpart K at § 493.1267 list only those portions that apply to cytogenetic testing so that, for example, the general requirement for testing positive and negative controls is not referenced. The commenter suggested at the very least, Appendix C (Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services) of the State Operations Manual (CMS Pub. 7) should instruct CLIA surveyors to ignore this requirement when inspecting a cytogenetics laboratory.

Response: The task of delineating all applicable requirements of subpart K for each specialty or subspecialty of testing would require continuous revision and updating for new test systems and emerging technologies. For this reason, the requirement (now at § 493.1225) remains unchanged and continues to direct laboratories to comply with the requirements of subpart K that are applicable to the testing being performed. However, Appendix C of the State Operations Manual will give guidance to surveyors concerning the control requirements for clinical cytogenetics. As specified now at § 493.1256(e)(2), each day of use, the laboratory is required to test the positive and negative reactivity of staining materials to ensure predictable staining characteristics. Media must be checked for sterility and to ensure that it supports growth of the appropriate tissues as required now at § 493.1256(e)(4). As for materials to demonstrate chromosome abnormalities, for example, linkage, breakage, or translocation, Appendix C of the State Operations Manual (CMS Pub. 7) states that these materials are not routinely available; however, an alternative procedure for the immediate assessment and monitoring of all testing over time must be instituted by the laboratory as specified now at § 493.1256(h).

Comment: A few commenters stated laboratory testing of sex chromatin by Barr body analysis or by ''Y'' body analysis is not considered the standard of practice for the diagnosis of individuals with sex chromosome aneuploidy, citing the well documented frequency of mosaicism in individuals with sex chromosome aneuploidy that leads to false negatives. Therefore, they strongly recommend not employing this testing as a screening test and deleting it from the list of tests that are performed in cytogenetics laboratories.

Response: We agree with the commenters and are deleting the requirements pertaining to the performance of X and Y chromatin counts for sex determination that were formerly at § 493.1267(a). In this final rule at § 493.1276(c), we are now requiring full chromosome analysis for sex determination.

Comment: A few commenters questioned the requirement that chromosome resolution be sufficient to support the reported result. One commenter stated that this is a ''catch 22'' in that a low resolution study reported as normal in a patient with an abnormality only detectable at a higher level of resolution would be wrong, however, the low resolution analysis would be in support of the reported

normal diagnosis. The commenters suggested establishing a specific band level of resolution that would be dependent upon the type of study requested.

Response: We are revising the requirement formerly at § 493.1267(b) (now § 493.1276(b)(2)) for clarity. The requirement now states that the resolution used must be appropriate for the type of tissue or specimen, and that the type of study required is based on the clinical information provided to the laboratory.

Comment: One commenter suggested that substituting the words ''photographic karyotypes'' for ''photographs'' would correctly reflect what cytogeneticists read.

Response: We are adding new language to the CLIA regulation formerly at § 493.1267(c) (now at § 493.1276(a)) to specify karyotypes in addition to photographs.

Comment: A few commenters disagreed with the CLIA regulation requiring ''appropriate nomenclature'' and felt the CLIA regulation should require the use of the International System of Cytogenetic Nomenclature in reporting all cases because it is the only recognized system that exists and anything else would be homemade and impossible to interpret other than by that particular laboratory.

Response: We agree with the commenters and are replacing the words ''appropriate nomenclature'' formerly at § 493.1267(d) (now at § 493.1276(d)) with the words ''the International System of Cytogenetic Nomenclature.''

Comment: One commenter stated that failure rate is an aspect of cytogenetic testing and that it is not addressed by CLIA regulations. The commenter also stated that failure rate can provide valuable information about a laboratory's capabilities and be easily evaluated by an individual lacking specific expertise in cytogenetics. The commenter stated that accepted standards for study failure rates exist for the various types of tests done in cytogenetic laboratories.

Response: We agree that study and culture failure rates can be a useful tool in evaluating a cytogenetic laboratory's performance. However, the study must be evaluated carefully because many factors outside of the laboratory's control may influence the rates, for example, specimen transit time and conditions. In addition, what constitutes failure must be clearly defined. For this reason, we are not mandating failure rates but encourage laboratories to monitor these rates as part of a QA program.

Comment: One commenter recommended gestational alpha-fetoprotein (AFP) be recognized as an analyte. Gestational AFP testing should not be included under Immunology, where AFP is used as a tumor marker.

Response: Although the analyte alpha-fetoprotein may be used for genetic screening, the test does not entail chromosomal examination (that is, cytogenetics). Measurement of this analyte may be used for non-cytogenetic purposes. CLIA certifies laboratories in both the subspecialty of routine chemistry and general immunology for gestational and maternal AFP.

Section 493.1273 Standard: Immunohematological Collection, Processing, Dating Periods, Labeling and Distribution of Blood and Blood Products

Specific comments received and response to comments regarding § 493.1273 are set forth below.

Comment: One commenter requested the addition of requirements to § 493.1273 regarding the use of bar code systems for the identification of blood and blood products, stating that laboratories should document the accuracy of bar codes before putting the systems into use, and as a continuing part of quality assurance while the systems are in use.

Response: We agree with the commenter that the accuracy and ongoing reliability of bar code systems used for the identification of blood and blood products is an important quality issue for laboratories that use them. Laboratories involved in collecting, processing, dating, labeling, testing, and distributing blood and blood products are required to conform to the FDA requirements for blood and blood products at 21 CFR parts 606, 640, 21 CFR 610.40, and 610.53. Specifically, 21 CFR 606.121: Container label, permits the use of container labels that bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research, FDA, and refers to FDA's ''Guideline for Uniform Labeling of Blood and Blood Components,'' that addresses blood product labeling requirements, including standards for bar codes. Also, 21 CFR 606.140 requires the laboratory to have control procedures that provide for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.

Comment: A laboratory surveyor asked why CLIA personnel are responsible for surveying large sections of the FDA's regulations. Since CLIA is a self-funded program, the commenter wondered if the FDA reimbursed the CLIA program for these services.

Response: The commenter is correct in questioning the role of the CLIA surveyors' inspection responsibilities. We have corrected the citations from 21 CFR to specify in 42 CFR part 493 the exact requirements that must be met under the CLIA regulations. The revised citations are now at §§ 493.1105(a)(1)(i), 493.1271(a)(1) and (b). When reviewed, the actual time expended surveying sections of the FDA's regulation was minimal. Sister agencies such as the FDA and CMS frequently assist one another without charge when expenditures to provide such assistance are *de minimis.*

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity

In the February 28, 1992 final rule with comment period, the personnel requirements are located in subpart M and include qualification requirements for individuals to direct a laboratory performing high complexity testing. A phase-in period was provided for individuals with a doctoral degree to obtain board certification. In response to the publication of the date extension rules, we received comments suggesting that we develop alternative provisions to qualify individuals with a doctoral degree on the basis of laboratory training or experience, instead of requiring board certification. On December 28, 2001, we published a proposed rule in the **Federal Register** (66 FR 67163) that included provisions to end the phase-in period and revise and expand the qualifications required for an individual with a doctoral degree to direct a laboratory performing high complexity testing.

Following publication of the proposed rule, we received 113 comment letters, which contained approximately 300 comments. Of these, 168 comments agreed with one or more provisions in the proposed rule, 120 comments disagreed with at least one of the provisions, 6 comments addressed the education requirements, and 1 comment reflected misinterpretation of the proposed requirements. Fifty-three of the 113 comment letters specifically addressed qualification requirements for directors of laboratories performing histocompatibility testing.

Specific comments received and responses to comments regarding the proposed rule are set forth below.

Comment: The majority of the comments on the first provision (at the proposed and former § 493.1443(b)(3)(i)) agreed with requiring board certification

as a qualification requirement for individuals having a doctoral degree to serve as high complexity laboratory directors. These commenters emphasized the role of board certification in ensuring that individuals have specific training and experience, as well as uniform and broad-based clinical knowledge, skills and competencies. In addition, at the CLIAC meeting held on January 30, 2002 through January 31, 2002, CLIAC expressed strong support for board certification for laboratory directors and suggested the recent efforts of the boards to provide more flexible routes to certification would allow more individuals to meet the certification requirements. CLIAC and other commenters also felt that the documentation of continuing education required for retaining board certification is essential in ensuring that individuals maintain the professional abilities needed to direct laboratories that provide services in the multifaceted, constantly changing high complexity testing category. The few comments opposed to board certification indicated certification does not ensure the performance of individuals and that employee skill validation is the responsibility of the employer. These commenters also noted the absence of evidence documenting that certified individuals perform better than noncertified individuals.

Response: We agree with the comments supporting board certification and are maintaining the former requirements at § 493.1443(b)(3)(i) requiring board certification as one of the pathways for qualifying individuals with a doctoral degree as directors of laboratories performing high complexity testing. Although certification does not provide absolute assurance that individuals will effectively fulfill the responsibilities required of directors, it is a recognized benchmark of competency and an appropriate mechanism for qualifying individuals to serve as laboratory directors. In addition, the ongoing continuing education required by each of the HHS-approved boards to retain certification helps ensure these individuals maintain a current knowledge base.

Comment: A State Health Department and one laboratory professional organization requested that all HHS-approved boards and the criteria for board approval be listed in the regulations. One of these commenters asked whether the phrase ''* * * be certified and continue to be certified * * *'' included in the proposed rule at § 493.1443(b)(3)(i) means that HHS will require board recertification when required by an HHS-approved board. In addition, a few commenters disagreed with board recertification.

Response: A total of eight certification boards have been approved by HHS. Four boards are listed in the former regulations at § 493.1443(b)(3)(i): The American Board of Medical Microbiology; the American Board of Clinical Chemistry; the American Board of Bioanalysis; and the American Board of Medical Immunology. On July 8, 1996, we published a notice in the **Federal Register** (61 FR 35736), that announced HHS approval of two boards: The American Board of Histocompatibility and Immunogenetics and the American Board of Medical Genetics. In this final rule, we are announcing HHS-approval of two additional boards: the National Registry for Clinical Chemistry at the doctoral level and the American Board of Forensic Toxicology. However, in this final rule, we are deleting the reference at § 493.1443(b)(3)(i) to the specific boards approved by HHS. Currently, all HHS-approved boards are listed on the Internet at *http://www.cms.hhs.gov/clia/dirc/con.asp.* In the future, boards approved by HHS will also be listed in Appendix C of the State Operations Manual (CMS Pub. 7), subpart M. Removing the list of approved boards from the regulations and placing the list in Appendix C will allow greater flexibility to update the list of HHS-approved boards.

In response to the comments suggesting that the criteria for determining HHS-approval of certification boards be included in the regulations, we do not believe that regulations, which specify standards that must be met by covered entities, should include details of an administrative process. All boards approved by HHS have been determined to have comparable certification requirements. In the ''Conditions for Coverage of Services of Independent Laboratories'' published in the September 19, 1974 **Federal Register** (39 FR 33693), the laboratory director qualification requirements included provisions for qualifying individuals with a doctoral degree. One option was certification by one of three boards (American Board of Medical Microbiology, the American Board of Clinical Chemistry, and the American Board of Bioanalysis). Subsequently, all boards approved by HHS have been determined to have certification requirements comparable to those three boards originally recognized. Any board may request HHS approval by submitting their request for board certification to CMS. This information will be evaluated to determine if the board's certification requirements are comparable to those currently approved boards.

With respect to requiring recertification, it was always the intent of the former regulations, that individuals with a doctoral degree qualifying under § 493.1443(b)(3)(i) must be, and continue to be, certified by an HHS-approved board. If a board requires recertification and an individual fails to recertify and loses board certification, this individual would no longer meet the director qualification requirement at § 493.1443(b)(3)(i). In this final rule, and as proposed in the December 28, 2001 proposed rule, we are revising the language at § 493.1443(b)(3)(i) for clarification.

Comment: A number of comments agreed with the second provision (at proposed § 493.1443(b)(3)(ii)) allowing individuals having a doctoral degree, who are serving or have served as directors of laboratories performing high complexity testing under the current regulations' phase-in provision, to continue to qualify without obtaining board certification. However, a few commenters felt this provision should be temporary, with a date specified by which board certification would be required to maintain qualification. One commenter urged that a date be established (and not extended) to conclude this qualification provision. A State Health Department interpreted the requirements in this provision to mean that a total of 4 years of experience is required, and that the training and experience and director and/or supervisory experience cannot be gained concurrently. This commenter also suggested this experience be postdoctoral experience.

Response: We agree the second proposed qualification provision is needed to allow (''grandfather'') individuals who have served or are currently serving as directors of high complexity testing to continue to serve. We also agree that a date needs to be specified to conclude this qualification pathway and the training and experience requirements clarified; however, we do not agree that the training and experience must be postdoctoral. We believe laboratory training and experience obtained while an individual is working toward obtaining a doctoral degree is pertinent and appropriate, and should be considered as meeting the requirement.

In this final rule, at § 493.1443(b)(3)(ii), we are specifying February 24, 2003, as the effective date

for this final rule's personnel qualification requirements, and we are clarifying the training and experience requirements individuals must meet. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors. Individuals must, therefore, as of February 24, 2003, have at least 2 years of training or experience, or both; and 2 years of experience directing or supervising high complexity testing.

Comment: Several commenters (including one laboratory professional organization and one certification board) felt continuing education should be added as a requirement to the second proposed provision.

Response: We acknowledge that continuing education is important; however, the proposed rule did not include a continuing education component for this provision. In addition, when ''grandfathering'' individuals who are serving or who have served in a particular position, minimum qualification requirements are considered so as not to disenfranchise these individuals. Finally, while regulations specify minimum requirements, States, accreditation organizations, and certification boards may establish more stringent requirements.

Comment: The majority of the commenters were opposed to including the third provision (at proposed § 493.1443(b)(3)(iii)). While there was general agreement that training and experience is essential for direction of high complexity testing, a few commenters (including a certification board and a laboratory professional organization) noted that training and experience vary greatly and it would be inappropriate to use training and experience as sole criteria to qualify individuals with a doctoral degree to direct high complexity testing. CLIAC also recommended that this provision be eliminated because it would not provide adequate documentation of the knowledge and skills needed for directorship of high complexity testing, lacks a mechanism to ensure continued competency, and is not commensurate with the high complexity laboratory director responsibilities. Several commenters noted that this proposed qualification pathway might result in an increase in the quantity of individuals qualified to direct high complexity testing at the expense of quality, which is in part attributed to a competent workforce. Although a few commenters agreed with this proposed provision to provide qualification specifications based on training and experience in lieu of board certification, they suggested revisions to make the provision more stringent and felt continuing education should be added to ensure that individuals maintain competency.

Response: We agree with the comments expressing disagreement with the third proposed qualification pathway and are not including it in this final rule. Although high complexity procedures comprise less than 20 percent of the laboratory procedures categorized, these are the most complex tests requiring a broad-based knowledge and the highest skills to fulfill the director responsibilities (formerly at § 493.1445) and ensure quality testing. Therefore, we believe the knowledge and training of a high complexity laboratory director with a doctoral degree can best be demonstrated through board certification. In addition, in the former regulations, we provided phase-in qualification requirements that allow individuals with a doctoral degree to qualify based on training and experience in lieu of board certification until the specified expiration date. As mentioned earlier, on five separate occasions, we extended the phase-in provision to allow time for directors who were not board certified to complete the certification requirements and for HHS to review and approve certification boards. During the 10 years the phase-in provision has been in affect, HHS has approved five additional boards and we believe sufficient time has been provided for individuals to become aware of the board certification requirement. Moreover, recent efforts of certification boards have provided additional routes to certification, allowing more individuals to meet the certification requirements.

In this final rule, board certification will be required for an individual with a doctoral degree seeking to become a high complexity laboratory director on and after February 24, 2003. However, as previously mentioned, we are allowing individuals, who qualified under the phase-in provision and are now serving or have served as directors of laboratories performing high complexity testing, to continue to serve as laboratory directors.

Comment: A few commenters disagreed with requiring a doctoral degree as the minimum education requirement for directors of laboratories performing high complexity testing. They suggested that individuals with an appropriate master's degree and progressive experience in the clinical laboratory (5 to 10 years) should be able to qualify.

Response: We believe the doctoral degree is an appropriate minimum education requirement for directors of laboratories performing high complexity testing. It is commensurate with the responsibilities of a high complexity laboratory director, as specified in the former regulations at § 493.1445, and consistent with the education requirements and responsibilities specified for the other laboratory personnel categories described in subpart M of the regulations.

Comment: Several commenters from local, county, and public health officials in a State disagreed with the doctoral degree requirement and cited the State Code that allows an individual with a baccalaureate or master's degree to direct a public health laboratory. The commenters noted that although the public health laboratories currently have a director who meets the CLIA regulations, many of these directors qualified under the former regulations at § 493.1443(b)(5), the ''grandfather'' provision that qualifies individuals if on or before February 28, 1992, they were qualified as a director under State law. Many of these directors will retire within 5 years.

Response: For the reasons stated previously, we believe the education requirements for directors of high complexity laboratories are appropriate and should not be lowered. In addition, as noted by the commenters, the February 28, 1992 final rule with comment period included a grandfather provision that qualified individuals that were serving as laboratory directors under State law on or before that date. We also provided a phase-in provision, which allows individuals with doctoral degrees time to obtain board certification by the specified expiration date. The phase-in provision was extended on multiple occasions and during this 10-year period HHS has approved five additional boards. We believe sufficient time has been provided for individuals to become aware of the requirements. In this regard, the State revised its statutes in a February 18, 1998 amendment and now requires any city or county public health laboratory and its personnel to comply with the CLIA regulations.

Comment: One commenter thought the proposed regulation would only allow physicians to serve as directors of laboratories performing high complexity testing.

Response: Although physicians with certain training or experience are qualified to serve as directors of laboratories performing high complexity testing, the notice of proposed rulemaking only included proposed revisions to the qualification requirements by which an individual with a doctoral degree may serve as a director of a laboratory that performs high complexity testing.

Comment: We received numerous comments on the qualification requirements for directors of laboratories performing histocompatibility testing. The majority of this group of commenters, which included the American Society of Histocompatibility and Immunogenetics (ASHI), and the American Board of Histocompatibility and Immunogenetics (ABHI), were in support of requiring specific histocompatibility training and experience for directors of laboratories performing histocompatibility testing. Specifically, they were in favor of requiring individuals with a doctoral degree to either meet the histocompatibility technical supervisor requirements specified in the former regulations at § 493.1449(o) and be certified by ABHI; or be serving or have served as a director of a histocompatibility laboratory and meet the histocompatibility technical supervisor requirements at § 493.1449(o). Opposing comments expressed concern that ASHI's proposal would exclude qualified individuals currently serving as directors of laboratories performing histocompatibility testing and is unnecessarily restrictive in an effort to protect the employment of those individuals who possess ABHI certification.

Response: We do not agree that the qualifications for directors of laboratories performing histocompatibility testing, which is categorized as high complexity testing, need to be revised to include specific histocompatibility training and education requirements. We note the revisions suggested by ASHI would establish higher director qualification requirements for individuals having a doctoral degree than for physicians who direct laboratories performing histocompatibility testing. In addition, these suggested changes to the qualifications for directors of laboratories performing histocompatibility testing would be inconsistent with the former qualifications required to direct laboratories performing other testing specialties. Although the commenters maintained that histocompatibility is highly complex and requires specialized skills for direction, other specialty areas (for example, cytogenetics and pathology) are also complex and require specialized technical expertise. Under the CLIA regulations, the requirements for specialty training and experience are included under the qualification requirements for the technical supervisor, which vary depending on the specialty of service. The December 28, 2001 proposed regulation did not include technical supervisor requirements, and we are not making any changes to the former requirements for technical supervisors.

In addition, several commenters mistakenly thought that having the director meet the histocompatibility technical supervisor requirements would eliminate the need for two individuals. Two individuals are only needed when a particular individual is unable to meet both the laboratory director and histocompatibility technical supervisor qualification requirements.

Finally, while regulations specify the minimum requirements for compliance, accreditation organizations may establish higher requirements for laboratory accreditation.

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory), High Complexity Testing, or Any Combination of These Tests

Following publication of the February 28, 1992 final rule with comment period, we received approximately 25 comments in reference to subpart P. The comments were in response to the requirements for enforcement of a written quality assurance policy. The laboratory's policy was required to address the ongoing and overall monitoring and evaluation of the quality of the total testing process and the laboratory's policies and procedures, identifying and correcting problems to ensure the accurate, reliable, and prompt reporting of test results, and to ensure the adequacy and competency of the staff. Over half of the comments received agreed with most of the requirements. Approximately 25 percent of the comments disagreed with some of the requirements or offered specific revised language.

Specific comments and responses regarding subpart P are set forth below.

Comment: One commenter suggested that the CLIA regulation specify who has primary responsibility for QA activities by adding a statement, for example, ''The laboratory director is responsible for ensuring that a quality assurance program is established and maintained.''

Response: We agree with the commenter. A requirement already appears at §§ 493.1407(e)(5) and 493.1445(e)(5), moderate complexity and high complexity laboratory director responsibilities, respectively, and states ''The laboratory director must ensure that the quality control and quality assessment programs are established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur.'' In addition, we are now providing an introduction at § 493.1200, subpart K that provides an overview of what quality systems include, the importance of ongoing assessment of these systems, and the laboratory's responsibility for establishment and maintenance of appropriate policies and procedures. The term ''quality assurance'' is synonymous with the term ''quality assessment.'' In addition, we are also making conforming changes (''assessment'' replaces ''assurance'') where appropriate.

Comment: One commenter suggested adding text at § 493.1709, Comparison of test results, that would acknowledge the role the manufacturer may have in verifying the accuracy and reliability of test results at least twice a year. Other commenters suggested language to clarify that tests not included under subpart I, performed by the laboratory at various (multiple) testing sites, must also be evaluated twice a year.

Response: Manufacturers are not precluded from providing services to laboratories to assist in verification of the accuracy and reliability of test procedures. However, it is ultimately the responsibility of the laboratory to develop and implement protocols for the biannual evaluation and comparison of test results obtained using the different methodologies and instruments employed by the laboratory and various testing sites the laboratory may have (for example, central laboratory, satellite laboratories, point-of-care testing). In addition, the laboratory must, twice a year, verify the accuracy of any test it performs that is not listed in subpart I. Therefore, we believe the requirements, formerly at § 493.1709 (now at §§ 493.1281 and 493.1236), clearly state the testing that must be evaluated and the requirements remain unchanged.

Comment: We received a comment agreeing with the requirement at § 493.1707, Proficiency testing assessment. The commenter stated that all proficiency testing (PT) results that were not correct should be investigated. Another commenter stated that all regulated analytes must be graded or the PT program must notify HHS and the

affected laboratory of any challenge, analyte, or test method for which it cannot produce a grade and the reasons why grading is not possible. A few commenters strongly disagreed with the practice of assigning a 100 percent score to PT analytes when the laboratory has not earned the score. The commenters stated that this practice penalizes laboratories that have correctly performed testing on all PT samples and causes laboratories that receive false representation of a grade to believe their test performance is exemplary, when it has not been comparatively evaluated. Additionally, laboratory testing problems that exist are not identified; therefore, no corrective actions are taken.

Response: Individual responses to the above comments are as follows:

• We agree with the commenter and are retaining the requirement formerly at § 493.1707 (now at § 493.1236) for the laboratory to review and evaluate results obtained on proficiency testing. PT result review is part of the QA process.

• We anticipate all regulated analytes (those listed in subpart I) will be graded by approved PT programs. The commenter is correct that, in some cases, not all challenges have been graded. Occasionally, as new methodologies or new instrumentation are developed for tests listed in subpart I, PT material is not always available or compatible with the new methods or instruments. In order to ensure that laboratories using new methodologies or instruments evaluate their performance, we are (now at § 493.1236(c)(2)) requiring laboratories to verify twice annually the accuracy of tests listed in subpart I for which compatible PT material is not available from approved programs.

• We agree with the commenter's recommendation to require PT programs to notify the laboratories and HHS of any challenge, analyte, or test method that cannot produce a grade and the reasons why grading is not possible. As CDC and CMS perform the annual review of PT programs required by the CLIA statute, programs must submit an annual report and, if needed, an interim report that identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples that adversely affect the programs' ability to evaluate laboratory performance. This requires PT programs to report problems to CMS. We are also requiring programs to notify laboratories (on the laboratory's PT results report) of exceptions and/or problems that precluded an analyte from being graded.

• We appreciate the commenters' concerns regarding false grading; however, there are reasons why false grading occurs. Almost all areas of testing under PT must be graded on an overall basis, that is, each analyte score under a subspecialty or specialty is averaged on each testing event to provide the laboratory with an overall subspecialty or overall specialty score. In order to determine an overall score, each analyte must receive a numerical score to allow the overall specialty or subspecialty to be graded. The circumstances that a PT program may assign an analyte score that does not reflect the laboratory's true test performance include: (1) Analyte evaluation does not produce at least 90 percent agreement among participant or referee laboratories that is required by regulation (the laboratory receives 100 percent score); (2) laboratory did not participate in the testing event (the laboratory receives zero percent score); or (3) laboratory's PT results were received after the cut-off date for receipt (the laboratory receives a score of zero percent for the late return of results). In response to the commenters' concerns, we are now requiring at § 493.1236(a)(2) that the laboratory verify the accuracy of the analytes for which a grade was assigned that did not reflect its true testing performance.

V. Provisions of the Final Rule

In response to public comments on the final rule with comment period and to provide policy clarifications, we made a number of changes in this final rule, which are summarized as follows:

Subpart A—General Provisions (Definitions)

• We added at § 493.2 the definitions for the terms ''calibration,'' ''calibration verification,'' ''FDA-cleared or approved test system,'' ''reportable range,'' and ''test system.''

• We revised § 493.3(b)(3) to remove the words ''National Institutes on Drug Abuse (NIDA)'' and add, in their place, the agency's new name, ''Substance Abuse and Mental Health Services Administration (SAMHSA).''

• We revised § 493.20 by removing the reference to ''subpart P'' and adding the cross reference to ''§ 493.1773.''

• We revised § 493.25 by removing the reference to ''subpart P'' and adding the cross reference to ''§ 493.1773.''

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

• We revised § 493.43(a) by removing the words ''tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests,'' and adding, in their place, the words ''nonwaived testing.''

• We revised § 493.45 by removing the reference to ''subpart P.''

• We revised § 493.47 by removing the reference to ''subpart P''.

• We revised § 493.47(c)(3) by removing the cross reference to ''§ 493.1776'' and adding, in its place, a cross reference to ''§§ 493.1773'' and ''493.1775.''

• We revised § 493.49 by removing the reference to ''subpart P.''

Subpart F—General Administration

• We added at § 493.643(c)(3)(ix) the word ''Clinical before the word ''Cytogenetics'' to correct a technical error. The word was inadvertently omitted from the final rule with comment period.

Subpart H—Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing

• We revised the heading of subpart H to read ''Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing.''

• We revised ''§ 493.801(a)(2)(ii)'' by removing the cross reference to ''§ 493.1709'' and adding, in its place, ''§ 493.1236(c)(1).''

• We revised ''§ 493.803(a)'' by removing the words ''tests of moderate complexity (including the subcategory), and/or high complexity'' and adding, in their place, the words ''nonwaived testing.''

• We revised the heading of § 493.807 to read ''Condition: Reinstatement of laboratories performing nonwaived testing.''

Subpart I—Proficiency Testing Programs for Nonwaived Testing

• We revised the heading of subpart I to read ''Proficiency Testing Programs for Nonwaived Testing.''

• We revised this subpart by changing the 90 percent consensus requirement to 80 percent consensus.

• We revised § 493.945 by removing the cross reference to ''§ 493.1257'' and adding in its place §§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2).''

Revisions to Subpart J and K

As stated in section II of this preamble (Highlights and Organization of Final Rule), we have consolidated and reorganized the requirements formerly in Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests, Subpart K—Quality Control for Tests of Moderate Complexity (Including the

Subcategory), High Complexity, or Any Combination of These Tests, and Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests, into a new Subpart J—Facility Administration for Nonwaived Testing, and Subpart K—Quality Systems for Nonwaived Testing. Below, we have only set forth substantive revisions to subparts J and K.

Subpart J—Facility Administration for Nonwaived Testing

- We revised the heading of subpart J to read Facility Administration for Nonwaived Testing.
- We revised subpart J to consist of §§ 493.1100 through 493.1105.
- We specified now at § 493.1100 that laboratories performing nonwaived testing must meet the applicable standard level requirements in §§ 493.1101 through 493.1105.
- We added the requirement now at § 493.1101(c) that laboratories must comply with Federal, State, and local requirements concerning laboratories and ensure that adequate safety precautions are in place to provide protection from laboratory hazards.
- We revised the language now at § 493.1101(d) (formerly at § 493.1204(b)) requiring safety procedures to be accessible rather than posted.
- We clarified the record keeping requirements now at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. This clarification applies to the requirements now at § 493.1771(c) and (d), and former §§ 493.1105, 493.1107, and 493.1221 introductory text.
- We removed the language formerly at § 493.1103(c) regarding laboratories providing oral instruction to patients as a supplement to written instructions, when appropriate.
- We clarified the requirement now at § 493.1103(d) (formerly at § 493.1271) that the facility must report transfusion reactions to the laboratories and, as appropriate, to Federal and State authorities.
- We revised the language now at § 493.1105(a)(3)(i) (formerly at § 493.1221) to specify that the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.
- We revised the language now at § 493.1105(a)(3)(ii) (formerly § 493.1107 introductory text) and § 493.1105(a)(6)(i) (formerly § 493.1109 introductory text) to specify the record retention requirements for immunohematology and blood and blood products to ensure consistency with the FDA requirements.
- We revised the requirement now at § 493.1105(a)(6) (formerly § 493.1109 introductory text) to remove the words ''exact duplicate'' and specify that the laboratory must be able to retrieve a copy of the original report.

Subpart K—Quality Systems for Nonwaived Testing

- We revised the heading of subpart K to read ''Quality Systems for Nonwaived Testing.''
- We revised subpart K to consist of §§ 493.1200 through 493.1299.
- We revised the introductory text now at § 493.1200 to provide an overview of quality systems, including the importance of ongoing assessment of these systems, and the laboratory's responsibility for establishment and maintenance of appropriate policies and procedures.
- We removed the lead-in paragraph formerly at § 493.1201(a) explaining the division between general QC and the QC for the specialties and subspecialties.
- We removed the requirement formerly at § 493.1201(a)(1) regarding the clearance process for alternative QC procedures that were never established by the FDA.
- We removed the requirement formerly at § 493.1203 regarding the clearance process for moderate complexity testing.
- We redesignated the requirement formerly at § 493.1205 regarding test methods, equipment, instrumentation, reagents, materials, and supplies. We incorporated the majority of these provisions into § 493.1252. The requirements formerly at § 493.1205(b) are now at § 493.1101(b) and the biologic product dating requirements formerly at § 493.1205(e) are now at § 493.1271(b).
- We removed the requirement formerly at § 493.1213(b)(1) regarding the QC clearance process for the manufacturer's process for verification of performance specifications for new patient testing devices introduced by the laboratory.
- We removed the requirement formerly at § 493.1215(a)(1) regarding the CLIA QC clearance process for maintenance of equipment, instruments, and test systems.
- We removed the requirement formerly at § 493.1217(a) regarding the CLIA QC clearance process for use of the manufacturer's instructions for calibration and calibration verification procedures.
- We removed the requirement formerly at § 493.1217(b)(2)(ii)(B)(1) (calibration verification requirement) regarding use of calibration materials traceable to a reference method or reference material of known value to allow flexibility in choosing material for calibration verification.
- We removed the requirements formerly at § 493.1225, the Condition of Microbiology, as it is a duplicate of the requirements under the Conditions of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology, now at §§ 493.1201, 493.1202, 493.1203, 493.1204, and 493.1205, respectively.
- We clarified the requirement now at § 493.1236 (formerly at § 493.1707) that laboratories must verify the accuracy of any analyte, specialty, or subspecialty when it is assigned a proficiency testing score that does not reflect laboratory test performance.
- We added the requirement now at § 493.1236(c)(2) that laboratories verify twice annually the accuracy of tests listed in subpart I for which compatible PT material is not available from approved PT programs.
- We removed the requirement formerly at § 493.1237, the Condition of Diagnostic Immunology, as it is a duplicate of the requirements under the Conditions of Syphilis Serology and General Immunology now at §§ 493.1207 and 493.1208, respectively.
- We revised the language now at § 493.1241(b) (formerly at § 493.1105) to clarify that an oral request for laboratory tests is permitted only if laboratory requests written or electronic authorization for testing within 30 days of the oral request and documents the efforts made to obtain a written or electronic authorization.
- We revised the language now at § 493.1241(c)(3) (formerly at § 493.1105(e) and (f)) to specify that the test requisition must solicit the patient's sex and age or date of birth.
- We added the requirement now at § 493.1241(c)(5) (formerly § 493.1105(f)) that the laboratory must ensure that the test requisition solicits the source of the specimen when appropriate.
- We revised the language now at § 493.1241(c)(7) (formerly at § 493.1105(e)) removing the age or date of birth requirement for Pap smear requisitions because it is now a requirement for all test requisitions at § 493.1241(c)(3).
- We revised the requirement now at § 493.1241(e) (formerly § 493.1701) to provide clarification that if the laboratory transcribes or enters test requisition or authorization information into a record system or laboratory information system, the laboratory must

ensure that the information is transcribed or entered accurately.

• We revised the requirement now at § 493.1242(a)(3) (formerly § 493.1105(f)) clarifying that the specimen source requirement, when appropriate, is part of the laboratory's submission, handling, and referral procedures.

• We removed the requirement formerly at § 493.1243, the Condition of Chemistry, as it is a duplicate requirement under the Conditions of Routine Chemistry at § 493.1210, Urinalysis at § 493.1211, Endocrinology at § 493.1212, and Toxicology at § 493.1213.

• We clarified the requirement now at § 493.1251(b)(13) (formerly at § 493.1211(b)(14)) that the procedure manual must include in the test procedure the laboratory's system for entering results in the patient record and reporting patient results including the protocol for reporting panic or alert values, when appropriate.

• We revised the language now at § 493.1251(d) (formerly at § 493.1211(d)) to provide that procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

• We revised the language now at § 493.1252(b) (formerly §§ 493.1202(c)(1) and 493.1205(c)) to specify that the laboratory's criteria for storage of reagents and specimens and test system operations must be consistent with the manufacturer's instructions, when available.

• We revised the language now at § 493.1253(a) (formerly at § 493.1213(a)) to provide that laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

• We revised the language now at § 493.1253(b)(1) (formerly at § 493.1213(b)(2)) by adding the words ''FDA-cleared or approved test system'' to the requirements regarding verification of performance specifications.

• We revised the heading now at § 493.1254 (formerly § 493.1215) to read ''Maintenance and function checks.''

• We revised the language now at § 493.1254(a)(2) (formerly at § 493.1215(b)(2)(ii)) regarding function checks by removing the word ''laboratory'' and adding, in its place, the word ''manufacturers.''

• We clarified the requirement now at § 493.1254(a)(2) (formerly at §§ 493.1202(c)(1) and 493.1215(b)(2)(ii)) to require that function checks be within the manufacturer's established limits before conducting patient testing.

• We removed the requirement formerly at § 493.1255, the Condition of Pathology, as it is a duplicate requirement under the Conditions of Histopathology, Oral Pathology and Cytology now at §§ 493.1219, 493.1220, and 493.1221, respectively.

• We revised the language now at § 493.1256 by removing the mandatory concurrent control testing requirements formerly at §§ 493.1237 Diagnostic immunology; 493.1239 Syphilis serology; and 493.1241 General immunology. We now require two levels of QC materials once each day of testing.

• We revised the language now at § 493.1256(d) (formerly at § 493.1218(b)) reducing the requirement by removing the specialty-specific control requirements (formerly at § 493.1253(b)) for automated hematology analyzers. We now require two levels of control materials once each day of testing.

• We revised the language now at § 493.1256(d)(3) (formerly at § 493.1218(b)) to clarify that QC materials are assayed or examined each day of patient testing.

• We revised the requirement now at § 493.1256(d)(3) for hematology by reducing the required frequency for control testing (formerly at § 493.1253(b)) from once each 8 hours of operation to once each day of testing.

• We added the requirement now at § 493.1256(d)(3)(v) that the laboratory must use a control system capable of detecting reaction inhibition when performing molecular amplification procedures in which inhibition is a significant source of false negative results.

• We removed the term ''drug abuse screening'' at § 493.1256(d)(4)(i), and added the term ''all known substances or drug groups'' identified and reported by the laboratory to accommodate the wider use of the technology.

• We revised the language now at § 493.1256(d)(5) (formerly at § 493.1218(b)(3)) to clarify that the laboratory must for each electrophoretic procedure, include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

• We revised the language now at § 493.1256(e)(2) (formerly § 493.1218(f)(2)) to clarify the use of staining materials.

• We clarified the use of calibration materials now at § 493.1256(d)(9) (formerly at § 493.1218(h)(2)) to provide that calibration material used as a control material must be from a different lot number than that used to establish a cut-off value or to calibrate the test system.

• We revised the requirement now at § 493.1261 by incorporating the bacteriology requirements formerly at § 493.1227.

• We revised the language now at § 493.1261 (formerly § 493.1227), reducing the requirements by removing the reference to specific control requirements in the subspecialty of bacteriology.

• We revised the requirement now at § 493.1262 by incorporating the mycobacteriology requirements formerly at § 493.1229.

• We added a requirement in mycobacteriology now at § 493.1262(a) (formerly § 493.1229(a)) for an acid fast control organism that produces a negative reaction.

• We revised the requirement now at § 493.1263 by incorporating the mycology requirements formerly at § 493.1231.

• We revised the requirement now at § 493.1263(a) (formerly at § 493.1218(f)(2)). We reduced the requirement to QC certain staining materials each day of use to only checking each batch, lot number, and shipment of lactophenol cotton blue when prepared or opened for intended reactivity.

• We revised the requirement now at § 493.1263(b) (formerly § 493.1213(d)) by reducing the requirement for daily testing to merely testing each batch of media and each lot number and shipment of antifungal agents before or concurrent with initial use.

• We revised the requirement now at § 493.1264 by incorporating the parasitology requirements formerly at § 493.1233.

• We revised the requirement now at § 493.1265 by incorporating the virology requirements formerly at § 493.1235.

• We removed the requirement formerly at § 493.1265(a)(10) that required the laboratory to use specific techniques such as mixed lymphocyte cultures to determine HLA Class II incompatibilities.

• We removed the requirement formerly at § 493.1265(a)(13) that required histocompatibility testing personnel to evaluate unknowns on a monthly basis because it is duplicative of the laboratory director responsibilities at § 493.1445(e).

• We revised the requirement now at § 493.1267 by incorporating the routine chemistry requirements formerly at § 493.1245.

• We revised the language now at § 493.1267(b) (formerly at §§ 493.1245(c) and (d)) by removing reference to the words ''calibration and calibration material'' from the blood gas requirements. However, we allow

calibration material as a control material provided it is from a different lot number than that used to calibrate the test system or establish a cut-off.

• We revised the requirements now at § 493.1269 by incorporating the hematology requirements formerly at § 493.1253.

• We revised the requirement now at § 493.1271 by incorporating the immunohematology requirements formerly at §§ 493.1239(e), 493.1241(d), 493.1269, 493.1273, 493.1275, 493.1283, and 493.1285.

• We revised the requirement now at §§ 493.1271(a)(1) and (b) (formerly §§ 493.1269(a) and 493.1273) to cite the specific 21 CFR requirements that must be met under the CLIA regulations.

• We revised the requirement now at § 493.1273 by incorporating the histopathology requirements formerly at § 493.1259.

• We added a requirement at § 493.1273(a) (formerly at § 493.1259) that the laboratory must check immunohistochemical stains for positive and negative reactivity each time of use in order to be consistent with the general QC requirements at § 493.1256(e)(3).

• We revised the language now at § 493.1273(c) (formerly at § 493.1259(b)) to add that an individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

• We revised the requirement now at § 493.1274 by incorporating the cytology requirements formerly at § 493.1257.

• We revised the language now at § 493.1274(d)(2)(iii) (formerly at § 493.1257(b)(2)) by removing the reference to gynecologic slides from the 200-workload limit that applies only to nongynecologic slides.

• We revised the language now at § 493.1274(e)(1) (formerly at 493.1257(c)(1)) by removing the requirement that a technical supervisor review cases categorized as reactive and reparative changes.

• We revised the requirement now at § 493.1276 (formerly at § 493.1267) by incorporating the clinical cytogenetics requirements.

• We clarified the requirement at § 493.1276(a) (formerly §§ 493.1107 and 493.1267(c)) by specifying that the laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification for karyotypes.

• We revised the requirement now at § 493.1276(b)(2) (formerly at § 493.1267(b)) to specify that the laboratory must have records that document that the resolution used was appropriate for the type of tissue or specimen, and the type of study required based on the clinical information provided to the laboratory.

• We revised the language now at § 493.1276(c) (formerly at § 493.1267(a)) by removing the requirements pertaining to the performance of X and Y chromatin counts for sex determination and requiring full chromosome analysis for sex determination.

• We revised the language now at § 493.1276(d) (formerly at § 493.1267(d)) by removing the reference to the words ''appropriate nomenclature'' and specifying that the laboratory report must use the International System of Cytogenetic Nomenclature.

• We revised the requirement now at § 493.1278 by incorporating the histocompatibilty requirements formerly at § 493.1265.

• We added the requirement now at § 493.1278(a)(3) that reagent specificity is required when reagent typing sera inventory is prepared in-house.

• We added requirements now at § 493.1278(b)(1) that the laboratory must use a technique that is established to optimally define, as applicable, HLA Class I and II specificity.

• We added requirements at § 493.1278(d)(1) and (d)(2) to specify that the laboratory must use a technique that detects HLA specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay, and use a method that distinguishes antibodies to HLA class II antigens from antibodies to Class I antigens.

• We revised the language now at § 493.1278(d)(4) and (d)(5) (formerly at 493.1265(a)(2)(ii) and (a)(8)(i)) to require laboratories to make a reasonable attempt to have available monthly serum specimens for periodic antibody screening and crossmatch, and have available and follow a written policy consistent with clinical transplant protocols for the frequency of performing antibody screening.

• We added the requirement now at § 493.1278(d)(7) to specify that for antibody screening, the laboratory must, as applicable, have available, and follow criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

• We revised the language now at § 493.1278(e)(1) (formerly § 493.1265(a)(1)(ii) to clarify that the techniques for crossmatching must be documented to have increased sensitivity in comparison to the basic complement-dependent microlymphocytoxicity assay.

• We revised the requirement now at § 493.1278(f)(1) (formerly at § 493.1265(b) and (c)) that requires specific testing protocols to be less prescriptive and allow laboratories to define testing policies and protocols for each type of cell, tissue, or organ to be transfused or transplanted.

• We clarified the requirement now at § 493.1278(f)(3) (formerly at § 493.1265(b)(3)) that the laboratory must have available, and follow, policies that address when HLA testing and final crossmatches are required for presensitized non-renal transplant recipients.

• We clarified the requirements now at § 493.1291(a) (formerly at § 493.1109(a)) to provide that the laboratory must have adequate systems in place to ensure test results and other patient specific data are accurately and reliably transmitted from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.

• We clarified the requirement at § 493.1291(c)(3) (formerly at §§ 493.1109 and 493.1109(a)) to specify that the date of the test report must be identified on the report.

• We clarified the requirement now at § 493.1291(c)(5) (formerly at § 493.1109) to indicate that the test report must include the specimen source, if applicable.

• We added language relevant to interpretation to the test report requirements now at § 493.1291(c)(6) (formerly § 493.1109(b)) for those test results that require supplemental information.

• We revised the language now at § 493.1291(j) (formerly § 493.1109(h)) by removing the words ''exact duplicate'' and clarified the language by specifying that all test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

Subpart M—Personnel for Nonwaived Testing

• We revised the heading of subpart M to read ''Personnel for Nonwaived Testing'' to conform with the names of the new subparts J and K.

• We revised § 493.1359(a)(3) by removing the reference to ''subpart P.''

• We revised § 493.1407(e)(5) by removing the word ''assurance'' and, adding in its place, the word ''assessment.''

• We revised § 493.1443(b)(3) to allow individuals with a doctoral degree who are serving or have served as directors of laboratories performing high complexity testing before February 24,

2003, under the phase-in provision, to continue to qualify as directors of laboratories performing high complexity testing.

• We revised the requirement at § 493.1443(b)(3)(i) by removing the list of HHS-approved boards. We are placing the list in Appendix C of the State Operation Manual (CMS Pub. 7) to allow more timely updates.

• We revised § 493.1445(e)(5) to refer to the quality assessment program.

• We revised § 493.1451(c)(4) by removing the reference to § 493.1257(c) and adding, in its place § 493.1274(d) and (e).

• We revised § 493.1471(b)(2) and § 493.1485(a) by removing ''§ 493.1257(d),'' and adding, in its place, ''§ 493.1274(c).''

Removal of Subpart P

As stated in section II of this preamble (Highlights and Organization of Final Rule), we incorporated the former ''Subpart P—Quality Assurance; Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests'' under the appropriate sections now located in Subpart K, General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems.

Subpart R—Enforcement Procedures

• We revised § 493.1844 by removing the reference to ''subpart P.''

Subpart T—Consultations

• We revised § 493.2001(e)(1) to read ''Criteria for categorizing nonwaived testing.''

• We revised § 493.2001(e)(4) to read ''Facility administration and quality systems standards;''

VI. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain new information collection requirements. Except as indicated below, all of the information collection burden in this final rule has been approved by the OMB under approval number 0938–0612 through June 2004.

Because the sections in this final rule are a reorganization of former sections, the burden approval numbers cited state the best approximation we could make for which combinations of former burden numbers match with the sections as specified in this final rule. Our approximations are as follows:

Section 493.1105 Standard: Retention Requirements

Under paragraph (a)(6), Test reports, the laboratory must retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting.

The change in this paragraph is that now the laboratory has the option of either retaining a copy of the report or having the capability of generating a copy of the report. This revision does not change the burden captured under OMB approval number 0938–0612.

Section 493.1241 Standard: Test Request

At paragraph (c), the laboratory must ensure that the written or electronic test requisition solicits the following:

• The sex and age or date of birth of the patient.

• The source of the specimen, as appropriate.

• The date and, if appropriate, time of specimen collection.

• Any additional information relevant and necessary to a specific test to ensure accurate and timely testing, and reporting of results, including interpretation, if applicable.

These new requirements mandate that laboratories solicit the sex and age or date of birth of the patient and, if appropriate, the source of the specimen and the time of specimen collection on the test request. In addition, the requirements clarify that the relevant information needed to ensure accurate and timely testing and reporting of results includes relevant information for interpretation of results.

We believe the burden of soliciting this information is minimal, as it is routinely captured by laboratories as part of good business practices. Therefore, while this information collection requirement is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 493.1242 Standard: Specimen Submission, Handling, and Referral

At paragraph (a), we are clarifying the requirement, formerly at § 493.1103(a), that the laboratory's written policies and procedures for specimen labeling specify that the patient's name or unique patient identifier, and when appropriate, specimen source be on the specimen label. This revision does not add additional reporting burden for this requirement under OMB approval number 0938–0612.

Section 493.1251 Standard: Procedure Manual

Paragraph (b)(13) requires that the procedure manual include the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting ''panic or alert values.''

This requirement, formerly at § 493.1211(b)(14), now includes the provision for a written procedure describing the laboratory's processes for entering results into patient records. This revision does not change the paperwork burden captured for this requirement under OMB approval number 0938–0612.

Section 493.1253 Standard: Establishment and Verification of Performance Specifications

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must, before reporting patient test results, demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the specified performance characteristics.

In addition, each laboratory that uses a test system in which performance specifications are not provided by the manufacturer, modifies an FDA-cleared or approved test system or introduces a test system not subject to FDA clearance or approval (includes standardized methods and methods developed in-house) must, before reporting patient test results, establish for each test system the performance specifications for specified performance characteristics.

Based upon the performance specifications verified or established, the laboratory must determine calibration procedures and control

procedures. Also, the laboratory must have documentation of the laboratory's performance of all activities specified in this section.

This is a 2-part requirement and will affect laboratories differently depending on whether they are verifying or establishing performance specifications for a test method. In addition, it only applies to new laboratories and new tests instituted in existing laboratories on and after April 24, 2003. Therefore, the number of laboratories needing to meet this requirement will be minimal. While this is a new requirement for some laboratories performing testing using unmodified, moderate complexity test systems approved or cleared by the FDA, it only applies to tests newly introduced into existing laboratories and to all tests in laboratories first established on or after April 24, 2003. In addition, it is common practice for test system manufacturers to perform or provide extensive assistance with this quality control activity when a laboratory buys or leases an instrument or other new test system. Thus, in practice, most of the burden for recording and documenting the quality control requirements are already born by the test system manufacturers. We do not believe that this burden will be shifted to the laboratory. Also, accrediting organizations and States with licensure programs, after which the CLIA requirements were modeled, have traditionally required laboratories to perform these activities. Therefore, while this information collection requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 493.1256 Control Procedures

These requirements were previously at § 493.1218 and approved under OMB approval number 0938–0612. The burden associated with these requirements involves the documentation of the control results and corrective action taken when control results do not meet the laboratory's acceptability criteria. Therefore, we are revising the paperwork requirements to some extent.

Under paragraph (d), the laboratory must do the following, as applicable:

- In paragraphs (d)(3)(i) and (ii), for each quantitative and qualitative procedure, include two control materials of different concentrations and a positive and negative control material, respectively.

There may be increased reporting for unmodified moderate complexity tests (formerly at § 493.1202(c)) whose manufacturer's instructions did not include these requirements. The burden for the remainder of the tests is captured for this requirement under OMB approval number 0938–0612.

- In paragraph (d)(3)(iii), for each semiquantitative procedure, include a negative control material and, as applicable, a control material with graded or titered reactivity.

There will be an increase in paperwork burden for unmodified moderate complexity tests (formerly at § 493.1202(c)) whose manufacturer's instructions did not include this requirement and for tests not subject to the specialty requirements formerly at §§ 493.1239(b) or 493.1241(a). The burden for the remainder of these tests for this requirement is captured under OMB approval number 0938–0612.

- In paragraph (d)(3)(v), for each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting inhibition.

There will be increased burden for recording the additional control results, when needed. The burden of recording the former control results is captured for this requirement under OMB approval number 0938–0612.

- In paragraph (d)(6), when a complete change of reagents is introduced, major preventive maintenance is performed, or any critical part that may influence test performance is replaced, the laboratory must, before resuming patient testing perform control material testing as specified under paragraph (d) of this section.

There will be an increase in burden for tests whose manufacturer's instructions did not include the requirements for control material testing specified under paragraph (d) of this section. The burden for the remainder of the tests is captured for this requirement under OMB approval number 0938–0612.

- Under paragraph (d)(10)(iii), when control materials providing quantitative results are used, statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

There will be an increase in reporting for moderate complexity tests formerly subject to the phase-in at § 493.1202(c). The burden for the remainder of these tests is captured under OMB approval number 0938–0612.

In paragraph (e)(3), the laboratory must check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. Therefore, reporting will increase from one to two control results in the subspecialty of histopathology for tests performed using immunohistochemical stains. For mycobacteriology, recording control results will increase from each week of use to each time of use for fluorochrome acid-fast stains. The burden of reporting one control result is captured for these requirements under OMB approval number 0938–0612.

Under the former OMB approval, we allotted 5 minutes per day for the reporting requirements in the former § 493.1218. This time allotment was based on the assumption that most of the previously unregulated laboratories were performing moderate complexity testing and ran a total of four QC samples daily. This time allotted included reporting for the burden associated with all the specialties and subspecialties; therefore, we believe the burden was slightly underestimated.

We are allotting 5 minutes per day to perform this documentation for the specialties and subspecialties (except bacteriology, mycobacteriology, hematology, and histopathology) and are adjusting this burden to reflect the number of laboratories currently affected by this rule. We are addressing the specialties and subspecialties of bacteriology, mycobacteriology, hematology, and histopathology separately. We are assuming laboratories are documenting control activities on an average of 6 days per week. Therefore, the burden for the specialties and subspecialties (except bacteriology, mycobacteriology, hematology and histopathology) can be calculated as 5 min./day × 24 days/month = 120 min./month = 2 hrs./month 2 hrs./month × 12 months/yr. = 24 hours/laboratory/yr.

The total estimated burden for this requirement (now at § 493.1256) is 27,685 laboratories (total number of laboratories minus the number of waived laboratories, provider performed microscopy (PPM) laboratories, and previously regulated laboratories) × 24 hrs./yr. = 664,440 hrs./yr.

Section 493.1261 Standard: Bacteriology

For the subspecialty of bacteriology, in this final rule at paragraph (a), the laboratory must check the following for positive and negative reactivity using control organisms:

- Each day of use for beta-lactamase methods other than Cefinase™.
- Each week of use for Gram stains.

• When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened and once every 6 months thereafter.

In paragraph (b), for antimicrobial susceptibility tests, the laboratory must check each batch of media, lot number, and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved reference organisms and, each day tests are performed, the appropriate control organisms must be used to check the procedure.

Former Burden

In the former regulation, laboratories had to check catalase, coagulase, beta-lactamase, and oxidase reagents using a positive and negative control material each day of use. In addition, the laboratories had to check bacitracin, optochin, ONPG, XV, X, and V disks or strips using a positive and negative control material each week of use. We estimate that most bacteriology laboratories operate an average of 6 days per week; therefore, we allowed an average of 2.5 minutes per day to document the results of control testing for the reagents listed above. This resulted in the former burden, 2.5 min./day × 24 days/month = 60 min./month = 1 hr./month 1 hr./month × 12 months/year = 12 hrs./laboratory/yr.

Under the former regulation, the estimated burden for documenting control testing for the reagents above was 27,443 bacteriology laboratories × 12 hrs./yr. = 329,316 hrs./yr.

Change in Burden

In this final rule, we are allowing laboratories to check each batch, lot number and shipment of reagents (catalase, coagulase, and oxidase), disks (bacitracin, optochin, ONPG, X, V, and XV), stains, antisera, and identification systems for positive and negative reactivity, and graded reactivity if applicable. For purposes of calculating the burden, we are assuming that laboratories receive a new shipment of reagents on the average of once per month. Since the burden with documenting control testing for susceptibility tests remain the same, we are considering the burden for documenting control testing for this subspecialty to be reduced by 2.5 min./day × 23 days/month = 57.5 min./month = 0.96 hrs./month 0.96 hrs./month × 12 months/yr. = 11.5 hours/ laboratory/yr.

The total estimated reduction in burden for this requirement is 27,443 bacteriology laboratories × 11.5 hrs./yr. = 315,595 hrs./yr.

Burden in This Final Rule

The estimated burden for documenting control testing for bacteriology reagents under this final rule is 329,316 hrs./yr.—315,595 hrs./yr. = 13,721 hrs./yr.

Section 493.1262 Standard: Mycobacteriology

For the subspecialty of mycobacteriology, in this final rule at paragraph (a), each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and with an acid-fast organism that produces a negative reaction.

Former Burden

In the former regulation, we included the requirements to document the results of control testing with the general QC procedures. However, since these documentation requirements are now under the condition, Analytic systems at § 493.1250, we have removed these documentation requirements from the general QC procedures and placed them in the subspecialty of mycobacteriology at § 493.1262.

In the former regulation, the laboratory was required, each day of use, to check all reagents or test procedures for mycobacteria identification with an acid-fast positive control organism (except the iron uptake test, which also requires a negative control). Assuming that only 35.4 percent (see section VII of this final rule, Regulatory Impact Analysis) of mycobacteriology laboratories perform identification procedures, and test an average of twice weekly, the former burden for documenting the positive control reaction for mycobacteria identification reagents and tests can be estimated as 2 min/day × 8 days/month = 16 min./month = 0.27 hrs./month × 12 months/yr. = 3.24 hrs./laboratory/yr.

The total estimated burden for documenting the positive control result is 1,127 mycobacteriology laboratories × 3.24 hrs./yr. = 3,651 hrs./yr.

As mentioned previously, the former regulation also required that the laboratory check positive and negative control materials for fluorochrome acid-fast stains each week of use and check a positive control material for other acid-fast stains each week of use. The former burden for all mycobacteriology laboratories to document these control results is estimated as 1 min/day × 4 days/month = 4 min./month × 12 months/yr. = 48 min./laboratory/yr. = 0.8 hrs./laboratory/yr.

The total estimated burden for documenting control testing for acid-fast and fluorochrome acid-fast stains is 3,185 mycobacteriology laboratories × 0.8 hrs./yr. = 2,548 hrs./yr.

The former total burden for documenting control testing for mycobacteria identification reagents and tests, and acid-fast, and fluorochrome acid-fast stains was 3,651 hrs./year + 2,548 hrs./year = 6,199 hrs/yr.

Change in Burden

Since documentation of the positive control reaction was previously required for mycobacteria identification reagents and tests and the number of laboratories performing mycobacteriology remains constant, we also estimated the increase in burden for documenting the negative control material for identification reagents and tests to be one-half the previous burden, which is ½ of 3,651 hrs./yr. (from above) = 1,826 hrs./yr.

The change in burden for increasing the frequency of acid-fast and fluorochrome acid-fast stains to daily and adding a negative acid-fast stain result is calculated as 1.5 min/day × 26 days/month = 39 min./month = 0.65 hrs./month × 12 months/yr. = 7.8 hrs./laboratory/yr.

The total increase in burden for these documentation requirements for acid-fast and fluorochrome acid-fast stains is 3,185 laboratories × 7.8 hrs./yr. = 24,843 hrs./yr.

The total increase in burden for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is 1,826 hrs./yr. + 24,843 hrs./yr. = 26,669 hrs./yr.

Burden in This Final Rule

The total estimated burden under this final rule for documenting control testing for mycobacteria identification reagents and tests, acid-fast, and fluorochrome acid-fast stains is 6,199 hrs./yr. + 26,669 hrs./yr. = 32,868 hrs./yr.

Section 493.1263 Standard: Mycology

In the former regulation for mycology, each week of use, the laboratory was required to check all procedures for mycological identification (including germ tube test) using an organism that produces a positive reaction. Under this final rule, the requirement is eliminated. This deletion results in the QC requirements for the germ tube test to default to the general QC requirements at § 493.1256(e)(1). The general requirements specify QC testing with each new batch, lot number or shipment of reagents. Because this is a minimal decrease (we estimate the change in frequency from weekly to monthly) in burden for documenting the result of a

single control, we are unable to accurately estimate the change.

Similarly, in paragraph (a), the laboratory must check each batch, lot number and shipment of lactophenol cotton blue for intended reactivity with control organism(s). Previously, control testing of this stain was required daily. As described above, since the decrease in this burden for documenting a single control result is minor, we are unable to accurately estimate the change.

Section 493.1269 Standard: Hematology

In the former regulations for the specialty of hematology, under paragraph (b), nonmanual hematology testing systems, excluding coagulation, the laboratory was required to include two levels of control materials each 8 hours of operation. In this final rule, this requirement has been revised from every 8 hours to each day of testing under § 493.1256 and results in decreased reporting.

The revisions to this requirement result in a decrease in documenting control results since the requirement has been revised from every 8 hours to each day of testing.

Previously, we had included these reporting requirements with the general QC procedures. However, since these requirements are now under the condition, Analytic systems, at § 493.1250, we have removed these hematology requirements from the general QC procedures and placed them under Control procedures at § 493.1256.

Former Burden: Hospital and Independent Laboratories

The total number of laboratories performing hematology testing is 32,753. Of this total, 5,329 are hospitals, 3,867 are independent laboratories, 17,844 are physician's office laboratories (POLs), and 5,713 fall into a miscellaneous category of others. We assume that this burden will affect most hospitals and independent laboratories since these laboratories typically operate 24 hours per day for 30 days a month. Therefore, the burden for these laboratories is 5 min./day × 30 days/month = 150 min./month = 2.5 hrs./month 2.5 hrs./month × 12 = 30 hrs./laboratory/yr. 9,196 hospital and independent laboratories × 30 hrs./yr. = 275,880 hrs./yr.

Change in Burden: Hospital and Independent Laboratories

Since this final rule will only require controls once a day, we are allowing a ⅔ decrease in burden for these laboratories. Therefore, the decrease in burden will be ⅔ of 275,880 hrs./yr. = 183,920 hrs/yr.

In addition, the new burden for hospital and independent laboratories is 275,880 hrs/yr.—183,920 hrs./yr. = 91,960 hrs./yr.

Former Burden: POLs

For POLs that only perform hematology for 8 hours a day, there is no reduction in burden. However, many POLs have operating hours that range from 9 to 10 hours a day and these laboratories are currently required to run control materials twice a day. In estimating the burden for this category of laboratories, we are including the POLs and the ''other'' category for a total of 23,557 laboratories. In addition, we estimate that 50 percent (11,779) of these laboratories operate on a 9 or 10-hour day for 20 days a month and must run control materials twice a day. Therefore, the burden is 3.5 min./day × 20 days/month = 70 min./month = 1.2 hrs./month × 12 months/yr. = 14 hours/laboratory/yr. × 11,779 laboratories (operating on a 9 or 10 hour day) = 164,906 hrs./yr.

The remaining 50 percent of the POLs that only operate on an 8-hour day have no change in burden that is, 1.75 min./day × 20 days/month = 35 min./month = 0.6 hrs./month 0.6 hrs./month × 12 months/yr. = 7 hours/laboratory/yr. 11,779 laboratories (operating on an 8-hour day) × 7 hours/yr. = 82,453 hrs./yr.

Change in Burden: POLs

In this final rule, all laboratories will only be required to run control materials once each day. Therefore, the POLs operating on a 9 or 10-hour schedule will have their burden decreased by 50 percent. The estimated decrease in burden for this group of laboratories under this requirement is 11,779 POLs (operating on 9 or 10 hour day) × 7 hrs./yr. = 82,453 hrs./yr.

Former Burden: Total

The total estimated burden was 275,880 hrs./yr. (hospital and independent laboratories) + 164,906 hrs./yr. (POLs operating on a 9 or 10 hour day) + 82,453 hrs./yr. (POLs operating on an 8 hour day) = 523,239 hrs./yr.

Change in Burden: Total

The total estimated decrease in burden for this requirement under this final rule is 183,920 hrs./yr. (hospital and independent laboratories) + 82,453 hrs./yr. (POLs) = 266,373 hrs./yr.

Burden in This Final Rule

The total estimated burden under this final rule is 91,960 hrs./yr. (hospital and independent laboratories) + 164,906 hrs./yr. (total POLs, those operating on a 9 or 10 hour day and those operating on an 8 hour day) = 256,866 hrs./yr.

Section 493.1273 Standard: Histopathology

The revisions to this requirement result in an increase in reporting from one control slide to two control slides for each group of slides for immunohistochemical stains. Previously, we included these reporting requirements with the general QC procedures. The requirements are now under the condition Analytic systems at § 493.1250 as requirements for Histopathology at § 493.1273. Although this is an increase in reporting from one control slide to two, we cannot estimate the laboratory burden because we do not know the number of laboratories that perform immunohistochemical stains or how often the staining is performed. Additionally, many of the laboratories performing immunohistochemical stains were already testing both a positive and negative control material, and some immunohistochemical stains can be checked for a negative reaction on the same slide that contains positive reactive cells. We expect that this revision will only affect a limited number of laboratories, and the increase in burden will be small.

Section 493.1278 Standard: Histocompatibility

In the former § 493.1265(a)(13), the laboratory was required to have, at least once each month, each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual had to be maintained. These requirements are deleted in this final rule.

Former Burden

There is a reduction in burden for this specialty since, in this final rule, we are no longer requiring the laboratories to, at least once each month, have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Therefore, we estimate that the former reporting burden for this activity to be 3 min./day for each individual, or 3 min./day × 1 month = 3 min./month × 12 months/yr. = 36 min/yr. = 0.6 hrs/individual/yr.

We estimate an average histocompatibility laboratory to employ three individuals. Therefore, the former

burden is three individuals × 0.6 hrs./yr. = 1.8 hrs/laboratory/yr.

There are 264 laboratories performing histocompatibility testing; therefore, the estimated burden for this requirement in this final rule is 264 histocompatibility laboratories × 1.8 hrs./yr. = 475 hrs./yr.

Change in Burden

Since this burden is not required in this final rule, we estimate the decrease in burden to be 475 hrs./yr.

Section 493.1291 Test Report

The following information collection requirements under paragraph (c) are new: The test report must indicate (1) either the patient's name and identification number or a unique patient identifier and identification number; (2) the test report date; and (3) the specimen source, when appropriate.

While this information collection requirement is subject to the PRA, we believe the burden with it is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs, ORDI, DRD–B, Attn: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VII. Regulatory Impact Analysis

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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 (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This regulation has no budget implications that impact Medicare benefit payments. We have, however, performed a complete regulatory impact analysis, although the specified thresholds to require a full analysis may not have been met.

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 $11.5 million or less in any 1 year. For purposes of the RFA, all laboratories are considered to be small entities. 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 604 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 an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule does not mandate any requirements for State, local, or tribal governments, or by the private sector. Therefore, we certify that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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 final rule does not significantly affect States' rights, roles, and responsibilities.

A. Executive Summary

This final rule includes changes that will impact many laboratories and indirectly impact manufacturers of test systems and controls. Most laboratories that perform nonwaived testing will be affected. This includes laboratories performing unmodified moderate complexity testing approved or cleared by the FDA, and laboratories testing in microbiology, syphilis serology, immunology, and hematology. Although we had insufficient data and information to calculate some of the costs and savings that may result from these changes, we estimate the overall impact will result in a savings of approximately $23 to $38 million the first year and $101 to $166 million over the next 5 years (Tables 1 and 2). The term ''savings'' as used in this RIA is defined as reduced compliance costs for laboratories subject to the CLIA regulations.

The most significant change in this final rule is related to the delayed effective dates (phase-in period) that allowed laboratories performing unmodified moderate complexity testing approved or cleared by the FDA to meet certain general QC requirements. Laboratories performing this type of testing did not have to verify methods before their introduction for patient testing or to periodically verify calibration. As shown in Table 1, we expect this change to immediately impact 29,601 Certificate of Compliance and COLA-accredited laboratories. We estimate the cost of completing the QC phase-in period to be between $28.3 million and $37.1 million the first year and between $124.1 and $162.5 million over the next 5 years.

Additional changes in this final rule will impact laboratories performing various specialties and subspecialties. The impact of these changes will vary depending on the volume and frequency of testing being done in each specialty or subspecialty.

Overall, the changes in microbiology will result in significant savings of approximately $55.9 million the first year and $245.2 million over the next 5 years. The changes in bacteriology and mycology are based on data demonstrating that for several reagents, QC is not required as frequently as required under the previous regulation. We assume the changes in bacteriology will affect 27,443 laboratories and result in immediate savings of $62.4 million and aggregate savings of $273.7 million over the next 5 years. In addition, we expect changes in mycology to affect 9,059 laboratories with immediate annual savings of $1.4 million and approximately $6.1 million savings over the next 5 years. For mycobacteriology, we are requiring more frequent QC testing and expecting this change to affect 3,185 laboratories with an estimated increase in costs of $7.9

million the first year and $34.6 million over the next 5 years.

Laboratories performing testing in syphilis serology (7,634), immunology (20,665), and hematology (32,753) can perform less frequent QC testing. We are unable to estimate the savings because we do not know how often the testing will be performed.

Finally, we are including a number of other changes that we are not considering burdensome. In many cases, we expect these other changes to have positive impacts; however, we are not able to quantify the consequences. Among these changes is the completion of the phase-in period for the laboratory director qualification requirement for high complexity testing that allowed an individual with a doctoral degree and the specified training and experience to qualify as a director of a laboratory performing high complexity testing in lieu of board certification up until December 31, 2002. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors. This means that on and after February 24, 2003, individuals with a doctoral degree who have not been grandfathered in as directors will need to be board certified to serve as directors of laboratories performing high complexity testing. The grandfather provision allows those individuals with a doctoral degree who have served or are currently serving as high complexity laboratory directors and have at least 2 years of training or experience, or both; and 2 years of experience directing or supervising high complexity testing as of December 31, 2002 to continue in this capacity without obtaining board certification. In the absence of this provision, the experienced individuals who have a doctoral degree without board certification and have served or are serving as directors of laboratories performing high complexity testing would be ineligible to continue serving as a director, resulting in costly and disruptive burdens associated with currently employed individuals obtaining board certification and laboratories replacing currently serving directors.

In summary, in the first year, we estimate the sum of all costs to be $36.2 to $45.0 million with savings of $63.8 million and a net saving of $18.8 to $27.6 million the first year. Over the next 5 years, we estimate the sum of all costs to be $158.7 to $197.3 million, a total saving of $279.8 million, and a net saving of $82.5 to $121.0 million.

In addition to overall monetary savings, this analysis acknowledges the potential for improvements in test accuracy and lower error rates in patient testing. We expect there to be improvements in the accuracy of patient testing and in accuracy of moderate complexity testing resulting from performance of method verification and calibration verification, and additional QC testing in mycobacteriology. We also expect more timely identification of potential laboratory errors resulting from the grading of more proficiency testing (PT) challenges.

TABLE 1.—IMPACTS DUE TO REGULATORY CHANGES: FIRST YEAR AND 5 YEAR TOTALS

	First year		5 Year total	
	Labs affected	Savings (costs) †	Labs affected	Savings (costs) †
Method Verification	11,248	($11.3–20.1)	29,601	($49.6–88.0)
Calibration Verification	29,601	(17.0)	29,601	(74.5)
Microbiology Changes				
Bacteriology	27,443	62.4	27,443	273.7
Mycology	9,059	1.4	9,059	6.1
Mycobacteriology	3,185	(7.9)	3,185	(34.6)
Microbiology Total		55.9		245.2
Less QC for Other Specialties				
Syphilis serology	7,634	Unknown savings	7,634	Unknown savings
Immunology	20,665	Unknown savings	20,665	Unknown savings
Hematology	32,753	Unknown savings	32,753	Unknown savings
Total		18.8–27.6		82.5–121.0

†In millions of dollars.

TABLE 2.—IMPACTS DUE TO REGULATORY CHANGES: ANNUAL IMPACTS OVER 5 YEARS

	Savings (costs)†					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year total
Method Verification	($11.3–20.1)	($10.6–18.8)	($9.9–17.6)	($9.2–16.4)	($8.6–15.3)	($49.6–88.0)
Calibration Verification	(17.0)	(15.9)	(14.8)	(13.9)	(13.0)	(74.5)
Microbiology Changes:						
Bacteriology	62.4	58.3	54.5	50.9	47.6	273.7
Mycology	1.4	1.3	1.2	1.1	1.1	6.1
Mycobacteriology	(7.9)	(7.4)	(6.9)	(6.4)	(6.0)	(34.6)
Microbiology Total.	55.9	52.2	48.8	45.6	42.7	245.2
Less QC for Other Specialties:						
Syphilis serology	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Immunology	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown

TABLE 2.—IMPACTS DUE TO REGULATORY CHANGES: ANNUAL IMPACTS OVER 5 YEARS—Continued

	Savings (costs)†					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year total
Hematology	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Total	18.8–27.6	17.5–25.7	16.4–24.1	15.3–22.5	14.4–21.1	82.5–121.0

† In millions of dollars.
Changes discounted at 7 percent compounded annually after Year 1.

B. Introduction

The changes in this final rule will have some impact upon nearly all laboratories performing nonwaived testing. The nature and magnitude of the specific effects on any particular laboratory will depend upon the volume and types of testing performed and the QC requirements it met under the former regulation. The most significant impact will be on laboratories performing unmodified moderate complexity testing approved or cleared by the FDA that have been following the minimal QC requirements provided during the QC phase-in period. With the completion of the phase-in, these laboratories may now be required to follow more stringent QC procedures.

QC Phase-in Requirements

Under the February 28, 1992 final rule with comment period implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), many laboratories that had never been regulated were required for the first time to establish and perform minimum QC and quality assurance practices. Most previously unregulated laboratories were performing primarily waived or moderate complexity testing using unmodified commercial test systems. Acknowledging the burden of coming under regulation for the first time, we created a phase-in period that allowed laboratories performing unmodified moderate complexity testing approved or cleared by the FDA to perform less stringent QC procedures than laboratories performing modified moderate complexity or high complexity testing. In addition, our intent was that when the phase-in period was complete, all laboratories performing nonwaived testing would be subject to the same QC requirements. This final rule is ending the phase-in period for QC that had been extended to December 31, 2002. The QC requirements for laboratories performing unmodified moderate complexity testing are now essentially equivalent to the requirements for modified moderate complexity, and high complexity testing.

As part of the QC phase-in, the FDA was to establish a process for review and clearance of manufacturers' test system instructions for compliance with certain CLIA QC requirements. This provision would have allowed laboratories to meet the CLIA QC requirements by following the manufacturers' FDA-approved or cleared instructions. However, because the CLIA program is user fee funded, we decided it would be prudent to wait until the phase-in period ended before implementing the FDA QC review. This afforded us the survey experience necessary to determine whether an additional FDA review process beyond that already in place as part of premarket review would be of benefit to laboratories. We realized through our experience inspecting laboratories that an additional FDA review would not be of such benefit. Therefore, this prospective provision was removed in this rule.

Moderate Complexity Testing

With implementation of this final rule, laboratories performing unmodified, FDA approved or cleared moderate complexity testing must now, as applicable—

- Augment procedure manual instructions;
- Monitor laboratory environmental conditions that affect reagent storage and test system operation;
- Verify or establish performance specifications for newly introduced test systems;
- Record or document equipment maintenance and function checks;
- Perform calibration verification; and
- Follow control procedures that monitor the accuracy and precision of the testing process.

These changes will primarily impact Certificate of Compliance and COLA-accredited laboratories, because these laboratories perform the bulk of the commercial, unmodified moderate complexity testing that was subject to the QC phase-in requirements.

Moderate and High Complexity Testing

This final rule updates requirements and recognizes the improvements in technology and stability of reagents by reducing the frequency of QC testing in several specialty and subspecialty areas that include both moderate and high complexity testing. For the following specialties and subspecialties, we reduced the frequency of QC testing, relieving laboratory burden and lowering the cost per test:

- Decreased frequency of QC testing for bacteriology and mycology reagent checks.
- Decreased frequency of QC testing for general immunology and syphilis serology to daily testing from concurrent with patient testing.
- Decreased frequency for hematology QC testing to each day of use from each 8 hours of operation.

For the subspecialty of mycobacteriology, we increased the frequency of QC testing for the following:

- Added a requirement for testing negative controls to check stains and reagents.
- Increased frequency for checking fluorochrome and acid fast stains.

Laboratory Director

We are completing the phase-in qualification requirements for high complexity laboratory director that allows individuals with a doctoral degree to qualify based on training and experience in lieu of board certification until February 24, 2003. With the implementation of this final rule on February 24, 2003, board certification will be required. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors. This new final rule permits those individuals who qualified under the

phase-in provision and have served or are serving as directors of laboratories performing high complexity testing and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue to serve as directors.

Miscellaneous Changes

There are a number of minor, miscellaneous changes. Some, like the change in the consensus requirements for PT grading from 90 percent to 80 percent, are the result of comments made to the former regulation. For the most part, these changes are considered to have no significant positive or negative impact. We consider many of them to be clarifications of implied requirements, or standard laboratory practices already in place, such as the requirement for laboratories to verify accuracy of analytes, subspecialties and specialties assigned a PT score that does not reflect the laboratories' actual test performance. In many cases, we have moved specific sections to make the regulation fit within the new regulatory framework (movement of the specimen through the laboratory) and to make the requirements easier to read and comprehend. While we expect positive benefits from these clarifications, it would be impossible to quantify these benefits.

C. Methodology and Approach

Basis for Estimates and Reliability of Projections

These projections are based upon some necessary assumptions concerning the current and future status of laboratory practices, technological advances, and the marketplace, making some degree of inaccuracy unavoidable. As each change is considered, the assumptions are stated. Due to the limitations in our data and information, we used a range of reasonable alternatives to estimate future events and reflect our degree of uncertainty. For much of this analysis, we use well-defined data from CMS Online Survey and Certification Reporting System (OSCAR) (2001) concerning laboratory demographics and test volume. When using less defined data, we made projections on the more costly side to provide an estimation of maximal impact.

We estimate the impact of these regulatory changes for those entities that these changes may affect, and we project the impact over the next 5 years. The completion of the QC phase-in period affects a portion of laboratories performing unmodified moderate complexity testing cleared by the FDA. Other changes in specialty and subspecialty QC requirements affect laboratories performing both moderate and high complexity testing. The changes in the high complexity laboratory director requirements primarily affect laboratories performing high complexity testing that need to hire a director on or after February 24, 2003. As appropriate for each specific change, in addition to the impacts on laboratories, we considered the potential impacts on manufacturers of laboratory test systems, controls, and calibration materials, and possible impacts on patients.

For this analysis, CDC used the services of Research Triangle Institute (RTI) to assist with data collection and cost-benefit analyses. RTI used data concerning current testing practices to estimate both immediate consequences and the impact over the next 5 years. A 7 percent discount rate was applied for projections after the first year, consistent with OMB recommendations (Economic Analysis of Federal Regulations under Executive Order 12866). Both RTI and HHS have sought data from a number of sources, including scientific articles, Government reports, CMS data, CDC studies, including data from CDC cooperative agreements, industry reports, reports by marketing consultants, interviews with manufacturers and laboratorians, and studies by professional groups, like the American Medical Association.

For each specific regulatory change, we outline the parties these changes will affect, methodological approach, necessary assumptions and limitations in the reliability of the conclusions, and possible alternatives.

D. Impacts

This discussion of regulatory impacts is organized as follows:

- Section 1 contains the demographics of the laboratories that the completion of the QC phase-in will impact.
- Section 2 has specific provisions not required during the phase-in period that certain laboratories will now need to meet.
- Section 3 has changes in specialty and subspecialty QC, including changes in microbiology, immunology, syphilis serology, and hematology.
- Section 4 has the completion of the phase-in requirements for laboratory directors.
- Section 5 contains miscellaneous changes, Including the change from 90 percent to 80 percent consensus requirements for PT results grading.

In this final rule impact analysis, for each regulatory change, as appropriate, our discussion is organized under the following topics:

- Rationale.
- Methodology.
- Benefits.
- Costs.
- Alternative approaches.

1. Laboratories Affected by Completion of the QC Phase-in Characteristics of Affected Laboratories Laboratory Demographics

The total number of certified and exempt laboratories in the United States (U.S.) is 174,856 (Table 5). This number includes a total of 168,688 CLIA-certified laboratories (96 percent), consisting of 91,540 laboratories with Certificates of Waiver (52 percent), 38,304 with Certificates for Provider-Performed Microscopy (PPM, 22 percent), 22,720 with Certificates of Compliance (13 percent), and 16,124 with Certificates of Accreditation (9 percent) (OSCAR, April 2001). In addition, there are 6,168 laboratories in the CLIA-exempt States of New York and Washington (4 percent).

This final rule will not affect the 74 percent of clinical laboratories holding Certificates of Waiver and PPM (129,844 laboratories). Laboratories with a Certificate of Waiver are only subject to limited CLIA requirements, they must only perform waived tests and tests cleared by the FDA for home use, follow manufacturer's instructions for testing, and maintain their waived certificates. Laboratories with a Certificate for PPM procedures must meet applicable requirements in subparts J and K of this final rule (formerly subparts J, K, and P). PPM procedures were not under the QC phase-in; therefore, PPM procedures were subject to the more stringent requirements in subpart K of the February 28, 1992 final rule with comment period. However, there are no QC materials for most PPM procedures.

For this analysis, we assume that all Certificate of Compliance laboratories perform some moderate complexity testing and that these laboratories have been meeting only the minimum QC requirements for FDA-cleared, unmodified moderate complexity test systems under the requirements of the QC phase-in period. In addition, we assume the completion of the QC phase-in would affect all of these laboratories (22,720 laboratories or 13 percent).

Similarly, we assume that the completion of the QC phase-in will affect the COLA-accredited laboratories because COLA's requirements are equivalent to the CLIA QC phase-in requirements. Therefore, these changes

will impact COLA laboratories (6,881 laboratories, 4 percent) when COLA revises its requirements to be equivalent to this final rule. Laboratories accredited by organizations other than COLA currently have QC requirements that are more stringent than those under the CLIA QC phase-in. With the adoption of the requirements in this final rule, CLIA requirements will more closely resemble these accrediting organizations' standards for QC.

Therefore, we estimate that these QC changes will immediately affect 29,601 laboratories (17 percent of the Nation's laboratories). These laboratories consist of those with a Certificate of Compliance (22,720) and COLA-accredited (6,881) laboratories. The 22,720 Certificate of Compliance laboratories that this QC change may affect consist of 1,392 Hospital (6 percent of laboratories with a Certificate of Compliance), 2,593 Independent (11 percent), 14,687 physician office laboratories (POLs) (65 percent), and 4,048 Other (18 percent) laboratories (Table 3). Since the majority of COLA laboratories are POLs (95 percent, COLA estimate), we assume all COLA laboratories are POLs for this analysis. The estimated total number of POLs that these QC changes will impact is 21,568, which comprise the largest portion of the 29,601 laboratories (73 percent) we estimated will be affected by this regulation. However, the affected POLs constitute only 22 percent of all U.S. POLs and 12 percent of all laboratories in the country. The vast majority (77 percent) of POLs hold Certificates of Waiver or PPM. In addition, changes in this final rule will not immediately affect most U.S. hospital laboratories because they are typically accredited, rather than Certificate of Compliance laboratories. The additional laboratory types in the CMS OSCAR (2001) database classified as ''Independent,'' are typically referral testing sites, and ''Other'' laboratories generally perform testing at a variety of healthcare sites including home health testing and nursing homes.

Although the percentages of laboratories with each certificate type remained relatively stable over the past several years, the absolute numbers show trends toward lower complexity certificates (waiver and PPM). For example, from 1998 to 2001, the number of laboratories with Certificates of Compliance decreased by 20 percent (5,604), and an increase occurred for both Waiver (+9 percent; 7,628) and PPM (+12 percent; 3,988) laboratories (Table 4). We expect this trend to continue in the future because of the widening availability of waived tests, many of which are considered important for on-site testing in POLs. Therefore, the long-term impact of this regulation may be mitigated by this continuing decrease in the number of Certificate of Compliance laboratories.

TABLE 3.—CERTIFICATE TYPE BY LABORATORY TYPE

Laboratory type [5]	Certificate type [1]										
	Compliance		Waiver		Accreditation		PPM		State exempt [4]		All
	N [2]	% [3]	N	%	N	%	N	%	N	%	N
Hospital	1,392	15	1,231	14	5,475	62	224	3	498	6	8,820
Independent	2,593	51	910	18	937	18	131	3	515	10	5,086
Physician Office	14,687	15	42,927	44	6,416	7	31,510	33	1,391	1	96,931
Other	4,048	7	46,472	76	3,296	5	6,439	10	3,764	2	64,019
All	22,720	13	91,540	53	16,124	10	38,304	22	6,168	2	174,856

[1] OSCAR, 2001.
[2] Number of Laboratories.
[3] Column Percent.
[4] Data from NY and WA States.
[5] Self Reported.

TABLE 4.—CHANGES IN CERTIFICATE TYPE, 1998 TO 2001

Certificate type [1]	1998		1999		2000		2001	
	N [2]	% [3]	N	%	N	%	N	%
Compliance	28,324	17	27,819	16	25,145	15	22,720	13
Waiver	83,912	52	87,754	52	89,998	52	91,540	54
Accreditation	16,469	10	17,337	10	15,885	9	16,124	10
PPM	34,316	21	36,789	22	37,535	22	38,304	22
All	163,021	100	169,700	100	171,736	100	171,010	100

[1] OSCAR, 2001.
[2] Number of Laboratories.
[3] Column Percent.

Specific Impact Dependent on Test Volume and Laboratory Type

Certificate of Compliance laboratories comprise 13 percent of U.S. laboratories and perform 991 million (19 percent) of the 5.3 billion tests annually in the U.S. (OSCAR, 2001). Our estimate of 5.3 billion tests for the year 2001 is consistent with the estimate of 5.9 billion tests for 1996 by Hoerger, Eggleston, Lindrooth and Basker (1997) and the estimate of 5.7 billion tests for the year 2000 in an Institute of Medicine report (Institute of Medicine, 2000). The average annual test volume per Certificate of Compliance laboratory is 43,618; however, the test volume distribution is skewed. Most (69 percent) Certificate of Compliance laboratories perform less than 10,000 tests per year, with 42 percent performing less than 2,000. For COLA laboratories, the average annual test volume is approximately 5,000 tests per laboratory (COLA, personal communication, June 2001), making the aggregate annual test volume for all

COLA laboratories 34 million tests. Among the Certificate of Compliance laboratories, POLs and laboratories under the classification as ''Other'' tend to have low annual test volumes, while Hospital and Independent laboratories have higher test volumes (Table 5).

This final rule will affect some aspect of these laboratories differently depending upon their annual test volume and the number of different test procedures they perform. Generally, laboratories performing a limited number of different tests will be impacted less than laboratories performing a greater number of tests. The low volume laboratories, POLs and Others, will be less impacted because they tend to have more limited test menus than those in Hospitals and Independent laboratories. However, the proportionate costs of testing are greater in low volume laboratories (Tershakovec, Brannon, Bennett, and Shannon, 1995) because of the overhead cost, including those related to CLIA.

Another major determinate of the impact of this final rule that correlates with test volume is the extent of quantitative testing performed using moderate complexity instrumentation. A CDC survey of laboratories found, for example, that among Certificate of Compliance laboratories, the use of quantitative testing instrumentation was extremely variable. Use of hematology analyzers varied from a low of 36 percent among Independent laboratories to a high of 77 percent among Hospital laboratories; for chemistry analyzers, the lowest frequency (20 percent) was among POLs, while Hospital laboratories had the highest use (83 percent) (Steindel, Rauch, Simon, and Handsfield, 2000). This survey was an unbiased on-site inventory of test systems and sampling was weighted to reflect the composition of U.S. laboratories.

We also anticipate that among Certificate of Compliance POLs, the practice size will affect the magnitude of the impact. Studies also show that practice size correlates directly with the extent of on-site testing (Ambulatory Sentinel Practitioner Network, 1996). Therefore, we expect the aggregate impact of this final rule to be less among solo practices since they perform less testing. However, solo practices have fewer employees and financial resources to execute aspects of this final rule, which may increase burden.

TABLE 5.—ANNUAL TEST VOLUMES BY LABORATORY TYPE, CERTIFICATE OF COMPLIANCE LABORATORIES ONLY, OSCAR, APRIL 2001

Laboratory type [1]	Total number of laboratories	Total number of tests [2]	Average number of tests per laboratory	Number and percent of laboratories grouped by annual test volume							
				≤2,00 tests/yr		2,000–10,000 tests/yr		10,000–25,000 tests/yr		>25,000 tests/yr	
				N [3]	% [4]	N	%	N	%	N	%
Hospital	1,392	354	254,310	444	32	56	4	148	11	744	53
Independent	2,593	307	118,396	572	22	481	18	433	17	1,107	43
Physician Office	14,687	147	10,008	6,899	47	4,681	32	1,617	11	1,490	10
Other	4,048	183	45,207	1,614	40	968	24	578	14	888	22
All	22,720	991	43,618	9,529	42	6,186	27	2,776	12	4,229	19

[1] Self-reported.
[2] In millions.
[3] Number of laboratories.
[4] Column percent.

2. Specific Changes Associated with Completion of the QC Phase-in Period

a. Procedure Manuals

Rationale

During the QC phase-in period, laboratories performing commercial, unmodified moderate complexity testing must ''have a procedure manual describing the processes for testing and reporting patient test results.'' With the completion of the phase-in, laboratories performing this type of testing will now be subject to more specific, comprehensive procedure manual requirements. Some laboratories may need to augment their current procedure manuals to meet the new requirements. Although we are unable to estimate the number of laboratories and the specific procedure manual changes they will need to make, we estimate that all Certificate of Compliance and COLA laboratories will require changes to their procedure manual.

In addition, laboratories must now document the dates of initial use and discontinuance for each procedure; and all procedures and procedural changes must be approved, signed, and dated by the current laboratory director before use.

Benefits

A comprehensive and up-to-date procedure manual is essential to ensure reliable and reproducible performance among individuals and is considered one hallmark of good laboratory practice and a necessary component of quality management.

Costs

For those Certificate of Compliance and COLA laboratories that need to amend procedure manual instructions, the cost will vary depending on the extent to which they may need to create procedural elements and the number of procedures performed in each laboratory. The cost for each laboratory will be the cost of the labor to augment documentation and the laboratory director's time in reviewing, signing, and dating procedures. We estimate that these costs will be minimal since most Certificate of Compliance and COLA laboratories do not perform a large number of test procedures and many may already have the documentation. We are unable to estimate the total cost for this requirement since we have no estimate on the extent to which procedure documentation will be necessary.

b. Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

Rationale

With the completion of the QC phase-in, laboratories performing commercial, unmodified moderate complexity testing must now meet the provisions at § 493.1252 for test systems, equipment, instruments, reagents, materials, and supplies. During the phase-in, these laboratories were required to ''follow the manufacturer's instructions for instrument or test system operation and test performance,'' which would include most of the requirements listed in § 493.1252. However, now laboratories must monitor and document conditions essential for ''proper storage of reagents and specimens, accurate and reliable test system operation and test result reporting.'' These conditions include ''water quality, temperature, humidity, and protection of equipment and instruments from electrical interruptions and fluctuations that adversely affect patient test results and test reports.''

Benefits

Monitoring and documenting environmental and other conditions necessary for proper reagent and specimen storage and test performance is essential to ensure quality test results. When conditions are outside of the prescribed acceptable range, corrective action can be taken. Without monitoring and documentation, laboratories may not be aware of conditions that may adversely affect patient test results.

Costs

The costs to implement this requirement will be minimal and will include labor to develop and maintain a monitoring and documentation system. We do not know the extent to which the specific commercial, moderate complexity procedures used in each laboratory will require monitoring of each of these conditions or the extent to which laboratories are already performing monitoring and documentation of these conditions. Therefore, we are unable to estimate a total cost for this requirement.

c. Method Verification

Rationale

Method verification is performed when a new test is brought into the laboratory and before beginning patient testing and result reporting. It consists of studies to verify that the laboratory can obtain accuracy, precision, reportable range and reference intervals with the new test system comparable to the manufacturer's specifications. During the QC phase-in period, laboratories could introduce testing using commercial, unmodified moderate complexity test systems approved or cleared by the FDA without verifying manufacturer's performance specifications (accuracy, precision, and reportable range of patient test results) before testing patient's specimens. On April 24, 2003, all laboratories must perform method verification when instituting any new moderate complexity test and before testing patient specimens, as specified in § 493.1253.

Methodology

To determine the possible impact, we did an estimate of the cost of assays to verify manufacturers' performance claims for commercial, unmodified moderate complexity tests expected to be introduced annually among the affected laboratories. For this analysis, we assumed that existing moderate complexity test systems would be retired and replaced with a new test system approximately every 5 years according to data available for a small population of laboratories. In addition, for cost calculations, we estimated the number of verification data points needed and the costs in terms of labor, materials, and reagents to perform these studies.

The cost of method verification is typically greater for quantitative tests than qualitative tests. In most cases, fewer specimens and less labor and reagents are required to verify the performance of qualitative tests. We do not know the fraction of new tests that are qualitative, so we treated all tests as if they are quantitative to calculate the maximal impact. Also, we assumed that the laboratories that this change will affect have not been performing method verification. However, we know that some manufacturers currently offer on-site verification assistance, and we expect that practice to continue; therefore, we may be overestimating the impact.

Estimates of the Incidence of New Test Introduction

Data describing how frequently new tests or test systems are introduced into laboratories were limited. For one estimate, we used the percentages of laboratories expected to add zero, one, two, three, four, or five moderate complexity tests to their test menus from a survey of laboratories participating in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network (LaBeau, Simon, and Steindel, 1999). Laboratories were asked how many nonwaived new tests they added to their test menus between April 1997 and April 1999. Although these percentages are for a 2-year time period, we conservatively assumed that all tests were adopted during the last year of the period. We assumed that the incidence of test introduction is roughly the same for the affected laboratories as for the Sentinel Monitoring Network. Multiplying these percentages by the total number of laboratories (29,601), we calculated the number of laboratories that are expected to add at least one test to their test menus in a year, approximately 11,248 (38 percent) (Table 6).

Estimate of Analyzer Replacement

Because of the small sample size, we were not confident that the survey of laboratories in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network accounted for the replacement of existing multiple analyte analyzers. Replacement of an obsolete analyzer with a new model requires verification for each analyte. Therefore, the cost of replacing analyzers depends upon the existing number of analyzers, the number of years of operation before replacement, the number of tests each analyzer performs, and the labor and reagent cost per assay for method verification. We assumed laboratories replace analyzers every 5 years and, therefore, compute the number of analyzers of each type that would require replacement each year by dividing the number of analyzers by five.

NICLTS data (Steindel, *et al* 2000) gave us the percentage of Certificate of Compliance POL, Hospital, Independent and Other laboratories having chemistry, hematology, therapeutic drug, ligand, reproductive hormone, and immunology analyzers. To determine the total number of each kind of analyzer to be replaced over the next 5 years, we multiplied these percentages by the number of Certificate of Compliance and COLA laboratories of each laboratory type to obtain the number of laboratories having each kind of analyzer, and then totaled the analyzers in each laboratory type (Table 7).

Benefits

To ensure accuracy and precision, it is especially important to demonstrate acceptable performance for a new test method before testing patient specimens. Comparing results of the new method with the manufacturer's claims and the current method, if the method is being replaced, can detect biases and problems with

reproducibility and linearity. Also, an evaluation of the appropriateness of the reference interval ensures that the test can differentiate a normal result from one suggesting a disease process. It is difficult to estimate the number of mistakes that can be averted by method verification. However, it is considered a hallmark of good laboratory practice to prevent errors when introducing a new test system, by verifying acceptable performance of the new methodology before testing patient specimens.

Costs

Number of Tests Needed To Verify Method Performance Specifications (Per Analyte)

There are no standards of practice established for method verification, and there is great variability in what laboratories currently do to verify performance specifications. The NCCLS has published several guidelines for verification of the elements of acceptable performance. One way to document performance is to use NCCLS protocols, document EP15–P for accuracy and precision, EP6–P for linearity (reportable range), and C28–A for reference intervals. The three separate protocols require a total of 120 assays, at a minimum. Reducing this number can be accomplished by performing some of the analyses together using the same specimens. Therefore, our estimate using the NCCLS protocol, in which we assumed a range of 120 to 150 assays per analyte or test, may overestimate the number of assays required.

Reagent Costs

We estimated the cost for reagents by obtaining price quotes from reagent manufacturers (Beckman-Coulter, Dade-Behring and Roche Diagnostics). Because the price estimates vary with test volumes, we assumed a moderate test volume with an average cost across analyzers to estimate an average reagent cost. We also estimated an average reagent cost to be $1.79 per test. We did not include costs for calibration or QC materials. However, many manufacturers provide assistance to laboratories for method verification, and this assistance many times includes providing reagents to the laboratory free of charge. Although manufacturers will incur some cost for reagents, the cost is significantly less than the retail sales price we quote.

Labor Estimates

Because we do not know the average number of analytes per test system, we assumed a broad range of analyst time (4 to 16 hours) at a rate of $17.90 per hour (Ward-Cook and Tannar, 2001). We are also assuming 1 hour of laboratory director time at a rate of $33.45 per hour (Bureau of Labor Statistics Occupational Outlook Handbook, 2000–2001 edition).

Materials

For the NCCLS approach, patient materials would suffice; however, these must be tested on a separate analyzer that serves as a reference for accuracy determinations. In addition, we are assuming that previously tested, stored patient samples would be used; therefore, we included locating previously tested patient materials in labor costs.

Total Costs

Based on the incidence of introduction of individual tests reported in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network survey (LaBeau, *et al* 1999), the cost of the requirement to perform method verification among affected laboratories can range from $8.3 to $15.3 million the first year (Table 6). Considering the costs of method verification for replacement analyzers, the costs can range between $3.0 and $4.8 million (Table 7). Therefore, the total first year expense for method verification may range from $11.3 to $20.1 million. The aggregate impact for method verification, with a discount over the next 5 years, may range from $49.6 to $88.0 million.

TABLE 6.—IMPACT OF METHOD VERIFICATION, NEW SINGLE TESTS

Number of tests	Percent adding	Number of laboratories adding	Number of tests added	Med tech labor cost (range)*	Lab director labor cost*	Total labor cost (range)*	Reagent cost (range)*	Total cost methods (range)
0	62	18,353	0	0	0	0	0	0
1	16	4,736	4,736	$0.34–1.36	$0.16	$0.50–$1.52	$1.02–1.27	$1.51–2.79
2	8	2,368	4,736	0.34–1.36	0.16	0.50–1.52	1.02–1.27	1.51–2.79
3	5	1,480	4,440	0.32–1.27	0.15	0.47–1.42	0.95–1.19	1.42–2.61
4	4	1,184	4,736	0.34–1.36	0.16	0.50–1.52	1.02–1.27	1.51–2.79
5	5	1,480	7,400	0.53–2.12	0.25	0.78–2.37	1.59–1.99	2.37–4.38
			26,048	1.87–7.47	0.88	2.75–8.35	5.60–6.99	8.32–15.33

* Millions of dollars

TABLE 7.—IMPACT OF METHOD VERIFICATION, ANALYZER REPLACEMENT

Analyzer type	Number of analyzers	Number of analyzers replaced each year	Medical technologist labor cost*	Laboratory director labor cost*	Total labor cost*	Reagent cost*	Total replacement cost*
TDM	3,230	646	$46.3–185.0	$21.6	$67.9–206.6	$0.45–0.56	$0.51–0.76
Chemistry	7,657	1,531	109.6–438.6	51.2	160.9–489.8	1.10–1.38	1.26–1.87
Hematology	12,439	2,488	178.1–712.5	83.2	261.3–795.7	0.27–0.34	0.53–1.13
Ligands	3,404	681	48.7–195.0	22.8	71.5–217.7	0.25–0.33	0.32–0.52
Reproduction	930	186	13.3–53.3	6.2	19.5–59.5	0.27–0.33	0.29–0.39
Immunology	223	45	3.2–12.8	1.5	4.7–14.3	0.06–0.08	0.07–0.09
			399.3–1,597.1	$186.5	585.8–1,783.7	2.18–2.72	2.98–4.77

TDM = Therapeutic drug Monitoring.
* Thousands of dollars.
* Millions of dollars.

Assumes tests per analyzer: TDM = 2, Chemistry = 15, Hematology = 1, Ligands, Reproduction & Immunology = 5

Assumes reagent cost per test: TDM = $2.88, Chemistry = $0.40, Hematology = $0.90, Ligands = $3.00, Reproduction = $2.38, Immunology = $2.38

Reliability of Estimates

The impact of method verification on any particular laboratory will depend on how many tests are introduced in any given year. The impact will be more on laboratories that are frequently expanding test menus, replacing test methods or test systems rather than those maintaining test menus and test systems. Obviously, any start-up laboratory performing nonwaived testing would be verifying the entire test menu. Nearly two-thirds of the laboratories in the Pacific Northwest Sentinel Network introduced no test systems during the 2-year interval and none introduced more than five (LaBeau, et al, 1999). Therefore, we believe while our estimates may accurately describe the impact on the universe of affected laboratories, for any particular laboratory, we may have underestimated or overestimated the consequences.

Discussions with manufacturers revealed that assistance with method verification is often included in the cost of buying or leasing an instrument or other new test system, regardless of the size of the laboratory. Regardless of whether the manufacturer assists in the verification process, the laboratory or the manufacturer or both will incur costs. What is relevant to the impact is whether the frequency of the method verification will change. Since method verification already frequently occurs in the absence of regulation and manufacturers often provide assistance, our estimate of the total cost of method verification probably overstates the incremental impact of the new requirement. However, we were unable to quantify how frequently method verification is performed currently, thereby preventing us from precisely estimating the incremental change in the frequency of method verification when this regulation becomes effective. Therefore, we may have overstated or understated the number of assays that laboratories will actually do to verify performance.

d. Calibration Verification

Rationale

During the phase-in period, laboratories performing unmodified moderate complexity testing cleared by the FDA performed testing without meeting the calibration verification requirement. On April 24, 2003, the phase-in period ends, and all laboratories must perform calibration verification at least every 6 months for each quantitative nonwaived test, as appropriate. Calibration verification is done to ensure that the test results are accurate throughout the reportable range of patient results for each test system.

Methodology

To determine the impact, we estimated the number of laboratories these changes will affect, their current menus of quantitative tests for which calibration verification would be applicable, the number of data points needed for verification and the costs in terms of labor, verification materials and reagents.

Number of Laboratories This Change Will Impact

We assumed that this QC change will affect all 29,601 laboratories, since Certificate of Compliance and COLA laboratories perform some moderate complexity testing. In addition, we assumed these laboratories have not been performing calibration verification on commercial, unmodified moderate complexity test systems.

Laboratory Menus of Tests With Verifiable Calibration

Calibration verification is performed for quantitative testing. For this analysis, we focused on multi-test clinical analyzers for which calibration verification materials are commercially available. Specifically, we estimated the fraction of laboratories that have analyzers for performing quantitative tests for chemistry, therapeutic drug monitoring, ligands, reproductive hormone testing, hematology, and immunology. By ''ligands'' we mean analytes measured by immunoassay, for example carcinoembryonic antigen, cortisol, and folate.

Number of Analytes Per Analyzer

For the purposes of estimating reagent consumption, we estimated the number of analytes being done by multi-test analyzers. We assumed that the variability of laboratory types and sizes would affect the number of different tests being performed; however, we were unable to account for the variability in this model. Because POLs comprise the largest portion of the laboratories that these changes will affect and POLs tend to have relatively limited test menus, we assumed most laboratory menus to be minimal among those laboratories that these changes will affect.

In order to estimate the number of analytes per laboratory, we analyzed data from three proficiency testing programs that target POLs (Medical Laboratory Evaluation, American Proficiency Institute, and College of American Pathologists' Excel) as a gauge of the numbers of tests offered among those laboratories these changes will affect. From these data, we estimated average test menus of fifteen chemistry analytes, two therapeutic drugs, one hematology analyte, and five for each ligand, immunology, and reproductive testing analyzer. Using this model, the specific number of analytes that must be verified has little impact on the estimates because most of the expense is in the verification kits.

Number of Data Points To Verify Calibration

At a minimum, laboratories must check three points in the reportable range to verify calibration, that is, the low, mid, and high points of the range. Although there is no requirement to perform duplicate testing at each level, it adds information about precision while adding very little to the cost of the procedure. Therefore, we included duplicate testing. We estimated that six data points are the minimum for adequate calibration verification, three concentrations in duplicate. Since calibration verification must be performed at least twice yearly, laboratories must collect a total of at least twelve data points for each analyte every year.

Benefits

We believe that calibration verification can reduce errors in patient testing by periodically providing information on the accuracy of an assay after it is calibrated, after any major maintenance or after problems are detected in routine QC. However, we are not aware of any studies demonstrating the affect of calibration verification on error rates.

Labor Costs

For estimates of labor costs, we assumed that 2 hours per year will be sufficient for each analyte for both performing the assay and inspecting the results for acceptable performance. This estimate may be too low in some instances and too high in others. The cost of the analyst time, $17.90 per hour, is the 2000 mean wage per hour for a staff medical technologist from Ward-Cook and Tannar (2001). In addition, we assumed that the labor cost of calibration verification per year is the

time we estimated it takes to perform the calibration verification (2 hours), multiplied by the analyst wage per hour ($17.90).

Cost of Verification Materials

Materials used for calibration verification span the reportable range of the method, and target values are assigned independently using accurate test methods. Acceptable materials are proficiency testing material, altered and unaltered previously tested patient specimens, primary standards or reference materials, independent calibrators, or materials for demonstrating linearity or calibration verification kits. For this analysis, we assumed laboratories will purchase calibration verification kits. However, all materials mentioned above may be used as long as the entire reportable range is tested with at least three concentrations and the nominal concentrations are independently assigned with a valid test methodology. Also, we assumed that a laboratory with any multi-test analyzer would buy a product to verify calibration of all tests the analyzer is capable of performing. We may be overestimating the cost because some laboratories do not perform all tests available on an analyzer, or we may be underestimating the cost by not including individual tests that may not be offered on a multi-test analyzer.

Our evaluation shows the costs were roughly similar for the various calibration verification products. The cost of calibration verification kits was obtained from several different suppliers of calibration verification materials (College of American Pathologists, CASCO NERL Diagnostics, Align, Sigma, R&D Systems, and Streck Laboratories). The average cost for a year's worth of calibration verification materials for comparable products was used as the cost of verification materials for each analyzer type .

Reagent Costs

We estimated the cost of reagents from price quotes by analyzer manufacturers (Beckman-Coulter, Dade-Behring, and Roche Diagnostics). This cost varies with test volume. We used the moderate volume estimate provided by these manufacturers for each analyzer type, since most of the laboratories that these changes will affect perform low to moderate test volumes. We calculated the total cost of reagents by multiplying the cost of reagents per test times the number of analytes per analyzer, the minimum number of tests per calibration verification, and the frequency of calibration verification, which we assumed to be, at a minimum, biannually.

Scope of Impact

Based upon these assumptions and estimates, we calculated the total cost of the requirement to perform calibration verification for laboratories that these changes will affect to be $17.0 million the first year, and the discounted cost will be $74.5 million by the end of the next 5 years (Table 8).

The impact to an individual laboratory will be proportional to the number of quantitative tests that need calibration verification. Larger laboratories with more analyzers and methods will need to perform calibration verification on more methods than smaller laboratories with fewer methods. Larger laboratories may also have more instrument repairs and reagent changes that may make it necessary to perform calibration verification more than twice a year. Therefore, large laboratories are more likely to incur a greater increase in the cost of calibration verification than small laboratories.

In addition, some manufacturers may furnish calibration verification materials and assist in the performance of calibration verification as part of their service. We cannot estimate the extent that this may happen; therefore, we may have overestimated the total cost.

TABLE 8.—IMPACT OF REQUIREMENT FOR CALIBRATION VERIFICATION

Test category	Laboratories affected for each test category	Labor costs per year	Cost of verification materials per year	Cost of reagents per year	Total costs per laboratory	Total costs per year †
Ther. Drug Monitoring *	3,230	$35.80	$413.00	$69.12	$517.77	$1.67
Chemistry	7,657	35.80	707.00	72.00	815.05	6.24
Hematology	12,439	35.80	575.00	10.80	621.60	7.73
Ligands	3,404	35.80	207.00	36.00	278.80	0.95
Reproductive	930	35.80	158.00	142.80	336.15	0.31
Immunology	223	35.80	150.00	142.80	328.10	0.07
Total	.....	.....	.....	.....	.....	16.98

* Therapeutic drug monitoring.
† Cost in millions.

e. Documentation of Maintenance and Function Checks

Rationale

During the QC phase-in period, laboratories performing commercial, unmodified moderate complexity testing were required to ''follow manufacturer's instructions for instrument or test system operation and test performance.'' Therefore, if the manufacturer had specific instrument maintenance procedures or function checks, the laboratories were required to perform them. With the completion of the phase-in, these laboratories must perform the maintenance and function checks according to the manufacturer, but also document their performance and results, as appropriate, and ensure that function checks are within the manufacturer's established limits before patient testing is conducted as specified in § 493.1254.

Benefits

Documentation of routine instrument maintenance and function checks provides a record for the laboratory to attest maintenance was performed according to the required schedule and to ensure that instrument function is within acceptable limits whenever patient testing is performed. This documentation is an essential element of good laboratory practice and laboratory quality management.

Costs

For those laboratories that have not been documenting maintenance and function checks, the cost to initiate this

process will depend on the labor needed to develop a documentation system. Subsequent costs will be for the labor necessary to maintain documentation, the number of instruments involved and the extent to which documentation is not currently being done. We have no data to estimate the total cost to fulfill this requirement; however, it will be of minimal impact.

f. Control Procedures

Rationale

The intent of the CLIA regulation was to impose the same requirements on all U.S. laboratories, regardless of testing site, in order to assure the public that minimum standards for quality testing were met wherever testing was performed. Under the QC phase-in requirements, laboratories performing testing using unmodified moderate complexity test systems approved or cleared by the FDA were required to test two levels of control materials each day of testing. Since many laboratories had never been regulated, they were given a phase-in period to allow them to become accustomed to meeting requirements for QC. During the phase-in, laboratories, could through the guidance in Appendix C of the State Operations Manual (SOM), use test system internal checks and controls, for example, built in procedural or electronic checks, as a substitute for one or both levels of traditional external liquid controls.

With the completion of the QC phase-in, all laboratories performing nonwaived testing are subject to the requirements specified in § 493.1256 for control procedures. The minimal number of control materials and frequency for control testing remains unchanged, two levels of control materials at least once each day of testing. We will continue to allow flexibility for laboratories to follow control procedures determined to be equivalent to testing two levels of external controls each day of testing.

We are acknowledging that laboratory technology has become simpler since the initial CLIA regulations were promulgated, and simplification and improvements are continuing. These technological advances may allow for control procedures equivalent to the traditional daily evaluation of two levels of external control materials, for example, the use of internal checks and internal controls or performance of control procedures at a frequency other than daily.

Additionally, laboratories must now meet some requirements for control use and acceptability that were not included for FDA-cleared, unmodified moderate complexity testing during the phase-in period. This includes testing controls in the same manner as patient specimens, rotating control testing among all operators who perform specific tests, and verifying the criteria for control results acceptability for quantitative tests.

Benefits

The requirements for control procedures between those in effect during the phase-in and this final rule are similar. While enforcement was permissive during the phase-in, there were no specific guidelines for laboratories to follow. With this final rule, laboratories will have guidance on what control procedures are acceptable (criteria will be specified in the SOM). In addition, the regulatory language is more specific, providing laboratories more detailed descriptions of what is required. Also, with the recognition that technology has and continues to improve, manufacturers will have more incentive to continue simplifying and improving technology to further reduce the cost of QC.

Costs

Most information on the prevalence of the reliance on internal checks and controls in lieu of using traditional external controls is anecdotal (American Association for Clinical Chemistry, 1999). A study by the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network (LaBeau, et al, 1999), demonstrates that the majority of the 83 laboratories completing the survey used mechanisms other than daily testing of traditional external liquid controls for a total of 184 nonwaived tests. These control mechanisms included built-in controls, procedural controls, electronic control cartridges or devices, and control strips. Although external controls were used with 85 percent of these tests, the frequency varied. Only 15 percent used external controls daily, while the majority of the laboratories (64 percent) used external controls with each kit or lot of reagents. However, this study sample size is too small to draw general conclusions about the use of control procedures in most laboratories. Since we anticipate maintaining the status quo allowing the use of internal checks and internal controls, and the testing of external control materials at the frequency currently being performed in most laboratories for unmodified moderate complexity testing, there will be no impact on the cost.

All laboratories must now verify control results acceptability for quantitative testing. Laboratories affected by the completion of the QC phase-in might incur costs to establish this practice, since this is a new requirement. This verification is simply done through repetitive testing to ensure that the laboratory's results are within the control manufacturer's statistical parameters for the particular test system in use. We have no data on the current prevalence of this activity for those laboratories that this change may affect. For laboratories that have not been performing this verification, the costs they will incur will be for the reagents and controls for replicate testing and for the labor in testing and evaluating the statistical parameters. In many cases, replicate control testing can be done concurrent with patient testing, if the control results are within the manufacturer's stated range, reducing the cost of this requirement. Laboratories not performing this verification will use controls at an increased rate; however, they may offset this cost by the ability to use more internal or procedural QC. We have insufficient data to estimate the total costs for this requirement.

Alternative Approaches

In revising these regulations, we considered maintaining the QC phase-in requirements for QC. These phase-in requirements were intended to temporarily exempt most previously unregulated laboratories from the more stringent QC requirements such as calibration verification and method verification. Previously unregulated laboratories have had sufficient time to become familiar with regulatory requirements. Although few studies have been done linking the performance of QC procedures with patient results (Astles, et al, 1998), the standards specified in this final rule are generally considered to be basic quality requirements. Also, to maintain the phase-in requirements would create a permanent inappropriate discrepancy between what is required among the laboratories having different types of certificates and between moderate and high complexity testing. Accredited laboratories, with the exception of those accredited by COLA, and State-exempt laboratories are already required to meet more stringent QC practices than those allowed during the phase-in. We believe the completion of the QC phase-in requirements is in the best interest of the public to ensure the minimum quality laboratory standards regardless of testing site and the type of testing performed.

3. Changes in Specialty and Subspecialty QC Requirements

a. Changes to Specific Microbiology QC Rationale

We are changing the requirements for some specific QC practices in microbiology in response to public comments, including recommendations made by the American Society for Microbiology (ASM). The changes affect the subspecialties of microbiology, including bacteriology, mycobacteriology, and mycology.

In 1996, the ASM (ASM, 1996) reported to the CLIAC a study of QC failures for 304 laboratories and nearly 15,000 commercial reagent lots representing 21 different bacteriology and mycology tests. QC failure rates for the reagents studied were 0.3 percent overall. The individual failure rate for each reagent was less than 2 percent, except for X factor strips/disks, which was 2.13 percent. The results of this study prompted the ASM to propose that reagent QC be required only with each new lot for commercial microbiology reagents having a 98 percent or greater success rate. On the basis of these study results and ASM's recommendations, in this regulation, we are lowering the required frequency for reagent QC for several bacteriology tests and two mycology tests (Table 9).

For mycobacteriology, we are increasing some QC requirements based on public comments, making them equivalent with standards that already exist (Table 9). False positive results have been reported in testing for M. tuberculosis (Burman, Stone, Reeves, et al, 1997). At the same time, the incidence of infection caused by other mycobacteria requiring additional testing for accurate identification is increasing significantly. To some extent, false positive results leading to inaccurate diagnoses and unnecessary or inappropriate therapy could be reduced by including a negative reagent control with biochemical identification tests. Therefore, in this regulation, negative controls are now required in addition to positive controls each day of use for mycobacteriology reagents. In addition, positive and negative controls are now required each day of use for acid-fast stains, and each time of use for fluorochrome stains. The revised requirements are justified by the important public health consequences of accurate and timely identification of mycobacteria, including M. tuberculosis.

TABLE 9.—CHANGES TO MICROBIOLOGY QC REQUIREMENTS

Existing regulations	New regulations (specified in this rule)
Bacteriology	
Each day of use, check catalase, coagulase, beta-lactamase and oxidase reagents and DNA probes using a positive and negative control.	(NC) Each day of use, check beta-lactamase, (other than cefinase (D)) and DNA probes using a positive and negative control.
Each week of use check bacitracin, optochin, ONPG, X, and V discs or strips using a positive and negative control.	(D) Check each batch, lot number and shipment of reagents (catalase, coagulase, and oxidase), disks (bacitracin, optochin, ONPG, X, V and XV), stains, antisera and identification systems for positive and negative reactivity, and graded reactivity if applicable.
Each month of use check antisera using a positive and negative control	(D) Check each batch, lot number and shipment of antisera when prepared or opened and once every 6 months thereafter using a positive and negative control.
Mycobacteriology	
Each day of use, check iron uptake test using a positive and negative acid-fast organism and check all other reagents or test procedures using a positive acid-fast organism.	(I) Each day of use, check all mycobacteriology reagents ((NC) iron uptake test) using a positive and negative acid-fast organism.
Each week of use check acid-fast stains using positive control	(I) Each day of use, check acid fast stains using a positive and negative controls.
Each week of use, check fluorochrome acid-fast stains using positive and negative controls.	(I) Each time of use, check fluorochrome stains using positive and negative controls.
Mycology	
Each day of use, test staining materials (lactophenol cotton blue) for intended reactivity.	(D) Check each batch, lot number and shipment of lactophenol cotton blue when prepared or opened for intended reactivity.
Each week of use, check biochemical tests and mycological identification tests (germ tube) with a positive control.	(D) Check each batch, lot number and shipment of reagents, disks, stains, antisera and identification systems for positive and negative reactivity.

D = Decreased QC Testing.
I = Increased QC Testing.
NC = No change.

Methodology

The number of laboratories impacted by the QC changes for the microbiology subspecialties of bacteriology, mycobacteriology, and mycology includes laboratories issued a Certificate of Compliance or a Certificate of Accreditation performing testing in the applicable subspecialties of microbiology according to the CMS OSCAR (2001) database. The number also includes the 1,448 laboratories performing testing in bacteriology, mycobacteriology, and mycology laboratories in the exempt States.

In estimating the cost of materials for changes to the microbiology QC requirements, we used information from several different microbiology reagent manufacturers and distributors (Remel, Becton Dickinson, and Fisher), including average list prices or suggested retail prices for reagents and supplies (we acknowledge some laboratories receive lower prices through negotiated discounts or purchasing agreements). We estimated the time and amount of reagent needed to perform QC testing and maintain records for the affected tests in the applicable subspecialties, through discussions with experts in microbiology.

For the tests the QC changes will affect, the cost of QC organisms was considered negligible since organisms may be preserved and recultivated on an ongoing basis. Although the cost of maintaining cultures, including media and supplies, and the time spent in preservation and recultivation may be considerable, the changes in this final rule will not cause complete elimination of QC organism testing; therefore, the cost of culture maintenance will not

change. On the other hand, in mycobacteriology, negative control organisms are now required for biochemical identification tests. Although this could result in some initial expense if new organisms must be purchased, significant cost should not be incurred, since in some cases the same organism may be used as a control for more than one test, and some of the organisms used for negative controls may be organisms already used as positive controls for different biochemical tests.

For estimating labor costs (the larger component of the QC cost for many tests), we used the 2000 mean wage per hour for a staff medical technologist (Ward-Cook and Tannar, 2001), divided by 60 minutes per hour to calculate the cost per minute ($0.30). The cost of labor is the sum of the time required to perform QC and maintain the QC records, multiplied by the calculated wage per minute. The total cost of QC per test is the sum of the labor and material costs.

Bacteriology

We estimate that the QC changes for bacteriology will affect 27,443 laboratories, consisting of 26,610 laboratories in the CMS OSCAR (2001) database and an additional 833 bacteriology laboratories in exempt States. The changes pertain to reagents commonly used to identify bacteria. Although these reagents are primarily used for high complexity culture and identification procedures that may not be performed in a number of physician office laboratories or laboratories that perform only moderate complexity testing, we included all bacteriology laboratories in our estimates because some physician office laboratories perform high complexity culture and identification procedures, and at least one of the reagents may be used for moderate complexity tests. We realize the number of bacteriology laboratories that these QC changes affect may be overestimated.

As recommended by ASM, we are reducing QC testing to every batch, lot number, and shipment, for 10 commercial bacteriology reagents. Under the previous QC requirements for catalase, coagulase, oxidase, and beta-lactamase, QC testing was additionally required each day of use. The previous QC requirements for bacitracin, optochin, ONPG, X, V, and XV strips and disks were to test each week of use after initial testing of each batch, lot number, and shipment of reagent. For antisera (including *Salmonella* and *Shigella* antisera), we are reducing the QC testing requirements from every month of use, to every 6 months after initial QC testing.

Mycobacteriology

We expect the QC changes will affect a total of 3,185 mycobacteriology laboratories in various degrees, depending upon the services they provide. This includes 2,903 laboratories in the CMS OSCAR (2001) database and 282 laboratories in exempt States. Based on estimates of the levels of mycobacteriology testing performed in the U.S. (CDC, 1995), all mycobacteriology laboratories perform acid-fast stains and could be impacted by the changes to the QC requirements for this testing. However, according to the estimates above, only 35.4 percent (1,127) of mycobacteriology laboratories perform mycobacterial organism identification, including 24.4 percent that perform acid-fast stains, primary culture, and identification (at least of *M. tuberculosis* complex), and 11.0 percent that perform acid-fast stains, primary culture, identification, and drug-susceptibility testing. Therefore, this number represents the maximum number of laboratories that could be fully impacted by all QC changes for this subspecialty.

For acid-fast stains, we are now requiring positive and negative control organisms to be QC tested each day of use rather than each week of use. In addition, we are now requiring that fluorochrome acid-fast stains be QC tested each time of use rather than each week of use. Although not all mycobacteriology laboratories perform both types of stains on a daily basis, the specific percentage of laboratories performing each type of stain is unavailable. We conservatively estimated that the QC change will affect all mycobacteriology laboratories for both staining procedures and will require the laboratories to perform QC testing for each procedure at least daily. However, professional standards of practice recommend QC for acid-fast stains each time of use, and the QC changes will not impact laboratories following these guidelines.

For conventional biochemical reagents and test procedures for mycobacterial identification from culture, we are now requiring that a negative control organism be tested in addition to a positive control organism each day of use. Based on the biochemical tests used for mycobacterial identification as listed in *Essential Procedures for Clinical Microbiology* (Eisenburg, 1998), we estimate 10 additional negative controls for biochemical tests may be performed by each laboratory depending on the organism to be identified. However, our estimates of the additional QC required and number of laboratories that these changes will impact could be inflated for several reasons. First, many mycobacteriology laboratories now use molecular methods for organism identification in lieu of conventional biochemical tests (we are not changing the QC requirements for molecular methods). According to an ASM survey presented to the CLIAC in 1999, 78 percent of the responding laboratories performing mycobacterial identification used molecular methods. It is likely that this percentage will increase in the future as new technology continues to be developed. Second, a significant number of mycobacteriology laboratories only identify *M. tuberculosis* and do not use biochemical tests to identify additional species of mycobacteria. Last, professional standards and at least one accreditation organization already recommend or require a negative control in addition to a positive control for each identification test; therefore, the increase in the requirement will not impact laboratories already meeting these standards. Since sufficient data are not available to quantify these considerations, we estimate a maximum of 35.4 percent of mycobacteriology laboratories will have to perform additional QC for conventional biochemical tests.

Mycology

We are reducing the QC testing for the germ tube test by eliminating the positive control each week of use after initial testing of positive and negative controls with every batch, lot number, and shipment. We are also reducing the QC testing for lactophenol cotton blue from checking this stain for intended reactivity each day of use, to requiring QC testing only with each batch, lot number, and shipment. We do not expect the QC changes to affect all 18,117 laboratories performing mycology testing (17,784 mycology laboratories in the CMS OSCAR (2001) database and 333 mycology laboratories in exempt States), since the impact of decreasing the QC testing will differ among laboratories depending on the testing performed and the numbers of positive cultures obtained by these laboratories. For both the germ tube test and the lactophenol cotton blue stain, we conservatively estimate that the reduction in QC testing will affect 50 percent of the total laboratories (9,059), those being hospital and independent laboratories that would perform the high complexity culture procedures that require the use of these reagents.

Benefits

Bacteriology

Reducing the QC testing requirements for bacteriology results in a significant decrease in costs for the laboratory, including savings in reagents, supplies, and labor. To estimate the impact of these reductions, the QC cost associated with the changes must be compared to the current cost of QC testing. We assumed laboratories are currently performing QC testing for each batch, lot number, and shipment of reagents; therefore, this practice is not affected by these QC changes. For catalase, coagulase, oxidase, and beta-lactamase, eliminating the daily QC requirement results in a savings for each of these tests equivalent to the cost of the daily QC. Similarly, by eliminating the weekly QC requirement for bacitracin, optochin, ONPG, X, V, and XV strips and disks, there is a savings for each of these tests equivalent to the cost of the weekly QC. For antisera (for example, *Salmonella, Shigella* typing sera), we are reducing QC testing from every month of use to testing once every 6 months after the initial QC testing of each batch, lot number, and shipment of reagent. Assuming an average shelf life of 2 years before expiration results in cost saving of 20 QC tests.

In addition to the direct financial savings in bacteriology laboratories, reducing the QC testing will also result in a time savings equal to the time previously required to perform the testing and maintain QC records on a daily, weekly, or monthly basis. This time saving could lead to increased productivity in bacteriology laboratories.

To calculate the savings by reducing requirements for QC testing in bacteriology, we estimated the baseline expenses per laboratory for performing each QC test. In calculations for beta-lactamase testing, as per the ASM study, we assume laboratories use Cefinase™ as their method of testing. After estimating the cost per individual QC test (positive and negative controls), we then determined the change in cost per day, week, and year (Table 10). In determining these changes, we considered the decrease in frequency of testing for each reagent (previously daily vs. weekly vs. monthly). To calculate weekly changes, we used an average of 6 days per week for laboratory operations, recognizing that while most hospital laboratories operate 7 days a week, physician office laboratories (that perform some culture and identification procedures) may only operate 5 days a week. Since we estimate all bacteriology laboratories use all tests for which QC is reduced, to determine the total annual savings per laboratory, we added the QC savings for each individual test.

To estimate the total annual savings in QC costs for all bacteriology laboratories, we multiplied the total annual savings per laboratory by the number of laboratories affected (27,443), and estimated a total cost savings of $62.4 million the first year.

TABLE 10.—CHANGE IN COST PER TEST FOR REVISED BACTERIOLOGY QC REQUIREMENTS

Reagent	Labor cost*	Reagent amount	Reagent cost	Total cost per test	Change in cost per day	Change in cost per week	Change in cost per year
Catalase	$0.60	1 drop	$0.08	$0.68	−$0.68	−$4.08	−$212.16
Coagulase	0.60	2 drops	0.17	0.77	−0.77	−4.62	−240.24
Oxidase	0.60	1 drop	0.06	0.66	−0.66	−3.96	−205.92
Cefinase	0.60	2 discs	2.65	3.25	−3.25	−19.50	−1,014.00
Bacitracin	0.60	2 discs	0.40	1.00	−0.17	−1.00	−52.00
Optochin	0.60	2 discs	0.33	0.93	−0.16	−0.93	−48.36
ONPG	0.60	2 discs	0.98	1.58	−0.26	−1.58	−82.16
X	0.60	2 strips	1.60	2.20	−0.37	−2.20	−114.40
V	0.60	2 strips	1.60	2.20	−0.37	−2.20	−114.40
XV	0.60	2 strips	1.60	2.20	−0.37	−2.20	−114.40
Antisera	0.60	2 drops	6.98	7.58	−0.24	−1.46	−75.80
Total							−2,273.84

*Labor cost estimate for each reagent includes one minute to perform QC test and one minute for recording and monitoring QC results.

Mycobacteriology

Erroneous test results can lead to inaccurate diagnoses and unnecessary or inappropriate therapy. When this pertains to *M. tuberculosis* or other mycobacteria currently emerging as significant pathogens, it could have substantial cost implications or adverse health outcomes due to the side effects of drugs used to treat infections caused by these organisms. Therefore, it is critical for laboratories to rapidly detect mycobacteria and accurately identify individual species within this genus. For laboratories performing acid-fast and/or fluorochrome acid-fast stains, accuracy is best ensured by including positive and negative controls each day (acid-fast) and each time (fluorochrome acid-fast) of use. For laboratories using conventional biochemical tests to identify mycobacteria, erroneous test results can most likely be prevented by including a positive and negative control organism for each test each day of use. Although difficult to quantify, the increased costs for additional QC testing are outweighed by the benefits of prompt, accurate mycobacterial detection and identification, and appropriate therapy for mycobacterial infections.

Mycology

Reducing the QC testing requirements for the germ tube test and lactophenol cotton blue stain will result in a cost and time savings for mycology laboratories. Since weekly QC is eliminated for the germ tube test, the financial savings will equal the cost of weekly QC, and the time savings will equal the time spent on a weekly basis performing and recording QC for this test. For lactophenol cotton blue, required QC testing each day of use is now eliminated. The cost and time savings resulting from this reduction is based on calculations assuming this test is performed an average of twice a week, when positive fungal cultures are detected.

We estimated the savings for QC testing in mycology by determining baseline expenses for each germ tube test labor ($0.90) and materials ($0.73), and each lactophenol cotton blue test labor ($0.60) and materials ($0.06), followed by calculation of the weekly and annual savings that will be realized

by reducing the QC frequency for these tests. Since we estimate that these changes will affect 50 percent of mycology laboratories, the total annual cost savings in mycology will be the annual savings per laboratory multiplied by half the number of mycology laboratories (9,059), an estimated total cost savings of $1.4 million the first year.

Costs

Mycobacteriology

We estimated the cost for the changes to mycobacteriology QC testing in the same manner as we estimated savings for bacteriology (Table 11). However, in mycobacteriology, not all laboratories will be affected for every test, since no more than 35.4 percent of laboratories perform organism identification. Therefore, when estimating the overall costs of increasing the mycobacteriology QC requirements, we considered the difference in the number of affected laboratories in the calculations.

When calculating costs for the acid-fast and fluorochrome acid-fast stains, we estimated that for each test, mycobacteriology laboratories would test two QC slides on at least a daily basis. Although QC is required each time of use for fluorochrome acid-fast stains (which can differ from each day of use), we assume QC would be performed daily and that each laboratory performs both acid-fast and fluorochrome acid-fast stains daily and will incur an increase in QC testing costs for both methods. However, some mycobacteriology laboratories use only one method of staining, and some laboratories already check QC slides each time of use. The percentage of laboratories using each type of stain exclusively or already performing QC each time of use is not available. Therefore, our estimate of the cost impact of this increase in QC testing is higher than the actual costs that will be incurred. When calculating the weekly QC testing costs for acid-fast stains, we used 7 days for laboratory operations, taking into account the CDC recommended turnaround time of 24 hours (Huebner, Good and Tokars, 1993) for reporting acid-fast smears.

TABLE 11.—CHANGE IN COST PER TEST FOR REVISED MYCOBACTERIOLOGY QC REQUIREMENTS

	Labor cost	Reagent amount	Reagent cost	Total cost per test	Change in cost per day	Change in cost per week	Change in cost per year
Identification Tests[1]	[2] $6.00	Variable	$20.46	$26.46	+$7.56	+$52.92	+$2,751.84
Acid-fast Stains	[3] 1.80	2–3 mL of 3 solutions	0.61	2.41	+2.41	+14.46	+751.92
Fluorochrome Stains	[3] 1.80	2–3 mL of 3 solutions	0.60	2.40	+2.40	+14.40	+748.80
Total							+4,252.56

[1] Estimate includes the following tests: arylsulfatase, 68 degree catalase, semi-quantitative catalase, NaCl tolerance, niacin, nitrate, pyrazinamidase, tellurite reduction, Tween 80 hydrolysis, and urease.
[2] Combined labor cost estimate for each reagent/test includes one minute to perform QC test and one minute for recording and monitoring QC results.
[3] Labor cost estimate for each stain procedure includes five minutes to perform QC test and one minute for recording and monitoring QC results.

For conventional biochemical reagents and identification procedures used on mycobacterial culture isolates, we calculated the potential cost increase for adding a negative control to each test based on 10 biochemical reagents (or tests) used for mycobacterial identification, as listed in Essential Procedures for Clinical Microbiology (Eisenburg, 1998). Although several additional biochemical tests can be used in the conventional scheme of mycobacterial identification, most of these tests were not included in our calculations since they are growth tests on certain selective media, which would not be subject to increased QC requirements. The iron-uptake test was also not included in our calculations since a negative control was previously required for this test. In estimating the change in cost for these identification procedures, the cost of labor for these tests was first calculated for a single test and then multiplied by 10. We assume the same approximate time is required to perform and record each QC test. The total reagent cost was determined by adding the cost of reagents for each individual test. The total cost for all 10 tests is the sum of the labor and reagent costs. Since in most laboratories these tests are performed less frequently than acid-fast stains or bacteriology identification tests, our estimates assume that each of these tests would be run twice per week. The additional cost for each laboratory per week is equal to twice the total cost for all 10 tests, and the additional annual cost per laboratory is estimated on the basis of this total weekly cost.

To estimate the total annual increase in the cost of QC for mycobacteriology, we multiplied the increased costs for acid-fast and fluorochrome stains by the total 3,185 mycobacteriology laboratories, and multiplied the increased costs for conventional biochemical identification tests by 35.4 percent of the total number of laboratories (1,127), and then added these amounts. We estimated the total cost increase would be $7.9 million the first year.

Error Rates

Bacteriology

We do not expect increased error rates in patient testing for the QC changes in bacteriology. As reported in the ASM study, the QC failure rates for laboratories participating in the study translated into one failure for all reagents surveyed every 53 years (ASM, 1996). Since in many cases, a single reagent or test is only a part of a bacterial identification scheme, these rare failures are not likely to lead to errors in organism identification or patient testing.

Mycology

We expect no additional errors as a result of the decreased requirements for QC in mycology.

Scope of Impact

The changes in QC requirements for microbiology laboratories will result in significant cost savings overall, on an annual and 5-year basis, when considering the net effect of the changes being implemented in the subspecialties of bacteriology, mycobacteriology, and mycology. The decreased QC requirements in bacteriology and mycology are expected to impact all U.S. laboratories performing this testing under a Certificate of Compliance, Certificate of Accreditation, or State exemption. We estimate the total cost savings for each microbiology laboratory

performing bacteriology testing to be $2,274 the first year. By multiplying this number by the total number of bacteriology laboratories (27,443), we estimate the total savings for bacteriology laboratories to be $62.4 million the first year and the overall savings over the next 5 years to be approximately $273.7 million for bacteriology.

For mycology, we estimate the total cost savings the first year per laboratory will be $153, and the change will affect 9,059 mycology laboratories with total savings of $1.4 million. We estimate overall savings will be $6.1 million for the next 5 years.

Although the increase in QC requirements for mycobacteriology will result in increased costs for microbiology laboratories conducting this testing, the impact will not affect all laboratories to the same extent, as previously explained. In fact, laboratories previously following professional standards of practice for mycobacteriology will not be impacted at all by these QC changes. Mycobacteriology laboratories will likely incur increased QC costs for acid-fast and/or fluorochrome stains, an estimated maximum increase of $1,501 per laboratory the first year, and $4.8 million overall, assuming laboratories use both methods of staining, and did not previously test controls each time of use. Since only 35.4 percent of mycobacteriology laboratories perform organism identification, the impact of increasing the QC requirements for certain identification tests will affect significantly fewer laboratories. We calculated this increase to cost $2,752 per laboratory the first year, with a maximum cost of $3.1 million overall. However, as explained previously in the Mycobacteriology subsection of the Methodology section, we believe this cost impact is overestimated for the increased QC for biochemical identification tests. Evidence shows that with newer technology, fewer laboratories use the older conventional tests, and this is expected to further decrease as technology continues to improve. In addition, laboratories offering limited services may not use as many biochemical identification tests if they only identify a limited number of organisms. Last, since professional standards and an accreditation organization already recommend or require negative control organisms, many laboratories may already be including the controls we are now requiring in this regulation. Therefore, the combined annual estimate of increased QC costs for mycobacteriology laboratories of $7.9 million overall and the next 5 year estimate of $34.6 million are likely inflated to some degree.

To summarize, the total savings in QC testing costs that will result from the changes in the microbiology requirements is the sum of the savings in the subspecialties of bacteriology and mycology, minus the cost increases in the subspecialty of mycobacteriology, a minimum total cost savings for microbiology laboratories of $55.9 million the first year. The savings projected over the next 5 years are approximately $245.2 million.

Alternative Approaches

For bacteriology and mycology, one alternative approach would be to continue to require QC testing for all reagents at the same frequencies as specified in the February 1992 regulations. However, there are no data that support continuing these frequencies to ensure the quality of patient testing. We believe if the previous frequencies were maintained, the total financial costs in labor and materials would far exceed the possible benefits in detecting problems with reagents. Another approach we considered is QC testing less frequently than with every batch, lot number and shipment of reagents (catalase, coagulase, beta-lactamase, oxidase, and germ tube test), disks and strips (bacitracin, optochin, ONPG, X, V, and XV), stains (lactophenol cotton blue), and antisera. However, because damage or improper handling of each batch, lot, or shipment can result in compromised reagent integrity, we did not consider this to be acceptable. We also considered leaving the requirement for monthly testing of antisera in place, but since there are no data to support this frequency, and the ASM data showed the reagents are relatively stable, we considered QC testing every 6 months adequate for these relatively expensive reagents with extended shelf lives.

For mycobacteriology, we considered not requiring a negative control with daily use of identification reagents, and not requiring QC daily for acid-fast stains, and each time of use for fluorochrome stains. However, the expense of increasing these requirements is relatively small because so few laboratories are impacted and in practice the incremental impact of adding a second control is relatively small. We cannot quantify the impact on error rates of not implementing these changes, but false positive tests in mycobacteriology can result in considerable extra expense in patient care.

b. Changes in Required QC Frequency for Syphilis Serology, Immunology, and Hematology

Syphilis Serology

We estimated that the reduction in frequency for syphilis serology QC testing may affect 7,634 laboratories (Certificate of Compliance (3,068), Certificate of Accreditation (4,070), and State-exempt (496)) (OSCAR, 2001 and the States of New York and Washington). Laboratories will be required to run controls each day patient specimens are tested, rather than each time they are tested. For laboratories testing patient specimens more than once a day, this change will result in a cost savings. However, we cannot estimate the amount of savings, because we do not know how many of these laboratories conduct testing more than once per day.

Immunology

There are a total of 20,665 laboratories (Certificate of Compliance (9,728), Certificate of Accreditation (10,285), and State-exempt (652)) performing immunology testing that may be affected by the reduction in the frequency for immunology QC testing. Under this final rule, laboratories must perform control procedures each day of testing, rather than concurrent with each testing event. We do not know how many of these laboratories test patient specimens more than once per day for each immunology procedure; therefore, we cannot estimate the cost savings if control procedures are performed less frequently. However, these provisions for the frequency of control testing do not supercede manufacturers' instructions or laboratory specifications that may require control testing more frequently; for example, each time patient specimens are tested.

Hematology

For hematology, we are reducing the required frequency for control testing from once each 8 hours of operation to once each day of testing. There are a total of 32,753 laboratories (Certificate of Compliance (16,332), Certificate of Accreditation (15,477), and State-exempt (944)) that perform hematology testing to which this change may apply. We do not know the exact number of laboratories that this change will affect because this change will only impact laboratories performing testing longer than 8 hours per day. However, we expect it will affect most hospital laboratories and many independent laboratories, since the majority of hospitals and independent laboratories operate 24 hours per day. For these

laboratories, if manufacturer instructions and laboratory specifications allow, performance of two control testing events per day can be eliminated for each hematology analyzer. Therefore, the aggregate savings may be significant, but we cannot estimate the impact.

Alternative Approaches

For these three changes, the aggregate impact will be a cost savings; however, we have insufficient information to estimate the reduced burden or savings in reduced analyst time, cost of reagents, and control materials associated with the reduced frequency of control material testing. We considered leaving the requirements for control procedures unchanged; however, based upon the current stability of the test systems used in these three areas, we have determined that few additional testing errors would be prevented by more frequent control testing.

4. Completion of Laboratory Director Phase-in

We are completing the phase-in qualification requirement for high complexity laboratory director that allows individuals with a doctoral degree to qualify based on training and experience in lieu of board certification. With the implementation of this final rule, board certification will be required under one provision. However, under the second provision, we are allowing individuals, who qualified under the phase-in provision and who have served or are now serving as directors of laboratories performing high complexity testing and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue to serve as laboratory directors. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors.

Rationale

Personnel qualifications are considered an essential benchmark of performance and requiring appropriate qualifications for the complexity level of testing performed by the laboratory is in the best interest of quality testing. High complexity testing requires more extensive knowledge, training, and experience to perform the management and administrative duties necessary to ensure that personnel are competent, methodologies are appropriate, and the quality control and quality assessment programs are suitable for the testing performed. The high complexity laboratory director qualification requirements in this final rule balance the quality concerns with the need to ensure continued access to high complexity testing.

Methodology

To determine the impact of these laboratory director qualification requirements over time on laboratories performing high complexity testing, we estimated the number of high complexity laboratories potentially impacted and the number of qualified individuals available to serve as high complexity laboratory directors during the next 5 years.

Laboratory Demographics

Using the CMS OSCAR (2001) database, we have determined that approximately 8,000 of the 22,720 Certificate of Compliance (COC) laboratories (35 percent, or 4.7 percent of all CLIA laboratories) perform some high complexity testing. To determine the total number of Certificate of Accreditation (COA) laboratories that perform high complexity testing, we included the approximately 9,200 laboratories accredited by five of the CLIA-approved accreditation organizations (American Association of Blood Banks, American Osteopathic Association, American Society for Histocompatibility and Immunogenetics, College of American Pathologists, and Joint Commission on Accreditation of Healthcare Organizations). The majority of these laboratories are independent or hospital-based and are assumed to perform some high complexity testing. We also estimated that approximately 1,700 of the 6,881 COLA-accredited laboratories (25 percent) perform some high complexity testing. In addition, the number of high complexity laboratories in the two CLIA-exempt States, New York (540) and Washington (235), is approximately 775 laboratories (New York and Washington, personal communication, March 2002). Therefore, the total number of CLIA laboratories (including New York and Washington) performing some high complexity testing in the United States is estimated to be approximately 19,700 laboratories.

As previously mentioned and illustrated at Table 4, the percentages of laboratories with each certificate type have remained stable over the past several years; however, the absolute numbers show trends toward lower complexity levels (waiver and PPM). While we expect this trend to continue in the future because of the widening availability of waived tests, we assume that COC laboratories switching to waiver and PPM certificates are those that perform only moderate complexity testing and the number of COC laboratories performing some high complexity testing will remain stable. In addition, we assume the number of accredited laboratories performing some high complexity testing will remain fairly stable, as has been the trend in the past several years.

High Complexity Laboratory Director Demographics

We also used the OSCAR (2001) database to identify the CLIA qualification requirements by which those individuals currently serving as laboratory directors of COC high complexity laboratories qualified. Using this data, we have calculated that 28 percent of these laboratories are directed by board-certified pathologists; 56 percent by licensed physicians with laboratory training or experience; 5 percent by individuals with doctoral degrees; 3 percent by individuals who have been serving as laboratory directors and were qualified as a laboratory director on or before February 28, 1992 (according to the March 14, 1990 final rule with comment period (55 FR 9538) published in the **Federal Register**); 7 percent by individuals who on or before February 28, 1992 were qualified under State law to direct a laboratory in the State in which the laboratory was located; and less than 1 percent by individuals who meet the qualifications currently at § 493.1443(b)(6) for the subspecialty of oral pathology.

We assume individuals currently serving as high complexity laboratory directors will retire at approximately the same rate as projected for the general population; that is, on average 3.8 percent per year for fiscal years 2001 through 2005 (U.S. Office of Personnel Management, Central Personnel Data Files, 2000). Therefore, we anticipate 3.8 percent of the approximately 19,700 high complexity laboratories (750) will need to hire a new laboratory director each year for the next 5 years. Pool of Individuals Qualified to Serve as High Complexity Laboratory Directors.

Using data (September 2000) from the American Board of Medical Specialties (ABMS), we estimated the total number of physicians that have 1 year of

laboratory training during medical residency to be 17,400. In addition, ABMS reports 5,784 pathologists received board certification over the past 10 years. This number is consistent with the Accreditation Council for Graduate Medical Education's (ACGME) data indicating there are approximately 2,660 anatomical and clinical pathology residents enrolled through the current academic year (ending June 2002). These residents will be eligible for board certification over the next 4 years.

The total number of board-certified doctoral-degreed individuals is estimated to be 2,090 (American Board of Bioanalysis (ABB), American Board of Clinical Chemistry (ABCC), American Board of Forensic Toxicology (ABFT), American Board of Medical Genetics (ABMG), American Board of Medical Laboratory Immunology (ABMLI), American Board of Medical Microbiology (ABMM), and National Registry of Certified Chemists (NRCC)). In addition, one HHS-approved board reports an average of 8 individuals receiving certification annually, another board reports an average of 11 annually, and a third board reports 37 annually (AAB, ABCC, ABFT, ABMLI, ABMM, NRCC, personal communication, March 2002).

Based on the data provided by the HHS-approved boards, ABMS, and ACGME, we believe there will be a sufficient number of individuals available to fill the possible 750 high complexity laboratory director vacancies per year over the next 5 years. Moreover, only 5 percent of the COC high complexity laboratories currently employ a laboratory director with a doctoral degree. We believe the percentage of COA and Washington State high complexity laboratories employing a laboratory director with a doctoral degree may be about the same or lower. Therefore, we estimate that approximately 180 of the 958 COC, COA, and Washington State high complexity laboratories that employ a doctoral-degreed individual as a laboratory director may have to replace their director during the next 5 years (36 annually). We did not include the high complexity laboratories in New York because they require laboratory directors to have ''specific'' training or experience in the specialty(ies) of testing the laboratory performs.

Benefits

Impact

There will be no immediate impact because the second provision included in this final rule allows individuals who have served or are currently serving as laboratory directors and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue in their capacity without obtaining board certification. This provision circumvents the costly and disruptive burdens associated with currently employed individuals obtaining board certification and laboratories, which perform high complexity testing, replacing currently serving directors.

With regard to future impact, available data indicate there are ample numbers of qualified individuals available to fill the estimated annual high complexity laboratory director vacancies over the next 5 years. In addition, the CLIA regulations permit qualified individuals to direct up to five laboratories, which may further lessen the burden associated with replacing retiring laboratory directors. However, States and accrediting organizations may have more stringent qualification requirements for laboratory directors and affected laboratories would need to continue to meet these requirements.

Costs

The provisions in this final rule at § 493.1443(b)(3), will have no immediate costs, and we believe the costs over the next 5 years will be no greater than the costs laboratories performing high complexity testing currently experience when replacing directors.

Alternative Approaches

In the December 28, 2001 proposed rule, we considered qualifying individuals with a doctoral degree and 6 years of laboratory training and experience, or both (including 2 years experience directing or supervising high complexity testing), as directors of laboratories performing high complexity testing. While we offered this as an alternative qualification pathway, we agree with the majority of commenters and the CLIAC recommendation that the provision is not commensurate with the responsibilities of a high complexity laboratory director or consistent with the qualification requirements and responsibilities specified for the other CLIA laboratory personnel categories. Moreover, we have determined that this qualification pathway is not needed to ensure a sufficient pool of qualified individuals to serve as high complexity laboratory directors and thus continued access to high complexity testing.

5. Miscellaneous Changes

The reorganization of this final rule reflects the flow of laboratory testing (from receipt of the specimen through test performance, test reporting and systems' assessments), eliminates duplicative requirements, and rewords certain requirements. In response to comments received to previous rulemakings, wherever possible we have made changes to the regulations to reduce the burden and expense to laboratories. Also, in recognition of new and emerging technologies and methodologies, obsolete requirements have been deleted and a few new requirements have been added. Listed below are several of these revisions, not yet discussed in this impact analysis, which may result in some change in costs or burden for laboratories. While we believe the change in costs or burden, or both, will be relatively minor, lack of data and information makes these estimates either difficult or impossible to quantify.

Revisions Resulting in No Change in Burden and Costs

The FDA QC review process was intended to be implemented when the QC phase-in ended, but we established through our survey process that the review would be not be of benefit to laboratories. Because this review was not implemented, there is no impact.

- Records of test system performance specifications established or verified as required under § 493.1253 must be retained for the period of time the test system is in use. Because this information provides important data about the laboratory's test system performance (for example, accuracy, precision, and reportable range of patient results) that the laboratory is required (formerly at § 493.1109(g), now at § 493.1291(e)) to provide to clients upon request, laboratories should have already been maintaining this information. Therefore, there is no additional burden with this change.
- When a laboratory transcribes or enters test requisition or authorization information into a record or information system, it must ensure that the information is transcribed or entered accurately. Formerly at § 493.1701, laboratories were responsible for identifying and correcting problems and ensuring accurate, reliable, and prompt reporting of test results. Inaccurate transcription of test requisition or authorization information would be one example of a problem, if left uncorrected, that could interfere with both the reporting of test results and the accuracy of the results. For this reason, we believe this new requirement should have no impact on the laboratory's burden or costs.

• Section 493.1254 now specifies that when using unmodified manufacturer's equipment, instrument or test systems, the laboratory must follow the manufacturer's instructions for maintenance and function check protocols rather than establish its own. While this revision results in a less stringent requirement than that specified under former § 493.1215, we do not anticipate a change (decrease) in burden or costs to the laboratory because following the manufacturer's instructions for maintenance and function checks when using unmodified equipment, instruments, or test systems was acceptable practice for meeting the former requirement.

• In the specialty of histocompatibility now at § 493.1278, the laboratory's reagent typing inventory must indicate reagent specificity as well as the previously required source, bleeding date and identification number, and volume remaining. Indicating a reagent's specificity in the laboratory's reagent inventory is routine laboratory practice that was inadvertently not addressed in the regulations. This new requirement for documentation of reagent specificity will have no impact on the laboratory's burden or costs.

Revisions Resulting in a Decrease in Burden or Costs.

• We are eliminating the requirement under the specialty of histocompatibility for each individual performing testing to evaluate previously tested specimens monthly as specified formerly at § 493.1265. The mechanism for and frequency of competency assessment of histocompatibility testing personnel will now be determined, as it is in all other laboratory specialties and subspecialties, by the laboratory's technical consultant or supervisor under §§ 493.1413(b)(8) and (9) and 493.1449(b)(8) and (9), respectively. Although this is a reduction in burden, we cannot estimate the cost savings.

• For laboratories performing histocompatibility testing, we are eliminating the specified frequencies for screening potential transplant recipient sera for performed HLA–A and B antibodies (formerly at § 493.1265(a)(8)(i)). Instead, in this final rule at § 493.1278(d)(5), we are requiring the laboratory to have available and follow a policy, consistent with clinical transplant protocols, for the frequency of such antibody screening. While this is most likely a reduction in burden, we cannot estimate the cost savings, since emerging data and research information will be an ongoing factor in determining appropriate screening frequencies.

• For the performance of non-renal transplantation in an emergency situation, we are eliminating the requirement that the results of final crossmatches be available before the transplantation when the recipient demonstrates presensitization by prior serum screening. In this final rule at § 493.1278(f)(3) (formerly at § 493.1265(b)(3)), the laboratory must have available, and follow, policies that address when HLA testing and final crossmatches are required for presensitized non-renal transplant recipients. We cannot estimate the savings from this reduction.

Revisions for Which There May Be a Negligible Increase in Burden or Costs

• The laboratory must ensure a uni-directional workflow for molecular amplification systems that are not contained in enclosed systems. This includes maintaining physically separate areas for specimen preparation, amplification and product detection and reagent preparation, as applicable. This is a recommended guideline for good laboratory practice by several laboratory professional organizations. Although we are unable to estimate the number of laboratories that perform molecular amplification with open systems without following the recommended guideline, we expect the number to be small and any increase in burden or cost with meeting this new requirement, now at § 493.1101, negligible.

• If the laboratory ceases operation, it must make provisions to ensure that all records, slides, blocks, and tissues are maintained for the applicable time frames. We anticipate that this change now at § 493.1105 will affect few laboratories; however, we cannot estimate the number or associated cost.

• In the former requirements at §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1) PT programs were required to grade PT results by first comparing the laboratory's response to the response which reflects agreement of either 90 percent of 10 or more referee laboratories or 90 percent or more of all participating laboratories. If this consensus agreement requirement was met, then the results could be graded based on their values relative to the established correct response for each PT analyte, subspecialty, or specialty. If the consensus requirement was not met, then laboratories were not graded and received an acceptable score, by default. As a consequence of this, a portion of those laboratories receiving ungraded PT results may have failed to recognize that their actual PT performance was not acceptable and only realized that their performance was unacceptable when their PT results were reviewed as part of an inspection. Thus, in some instances laboratories failed to make appropriate corrections to testing problems, identified by unacceptable PT performance, in a timely manner. Now at §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1), the consensus agreement requirement is lowered to 80 percent. Fewer PT results will be ungraded and a portion of those laboratories previously not graded due to a lack of consensus will receive an unacceptable PT grade. Thus, these laboratories will be alerted to potential testing problems sooner. Also, with the change at § 493.1236(b)(2), which now requires all laboratories to verify testing accuracy for any analyte, subspecialty, or specialty assigned a PT score that does not reflect the laboratory's actual PT performance, an additional number of laboratories may become cognizant of their poor testing performance sooner than when PT results are not graded and they receive an acceptable score by default. The combination of fewer ungraded PT results with the requirement for all laboratories to review and verify their PT results, especially when they are deemed questionable by the PT program, will result in these laboratories, in a more timely manner, identifying and correcting potential sources of error which may not have been otherwise detected, thereby increasing overall laboratory accuracy. However, there may be some burden for those laboratories that are now required to verify testing accuracy but are having no real problem with testing. Since verifying testing accuracy whenever there is a potential likelihood of error is generally regarded as good laboratory practice, and in most instances the laboratory's routine use of QC may be used to verify testing accuracy, this should not be considered burdensome. Likewise, PT programs may be slightly inconvenienced by the need to change their grading algorithms to accommodate the 80 percent consensus requirement. However, it is the responsibility of PT programs to assist laboratories in assessing their testing performance by providing PT samples that can be appropriately graded.

Although these changes may affect laboratories and PT programs, the impact is not quantifiable and is considered minor compared to the overall beneficial effect of improved laboratory testing accuracy.

• Test requisitions or other written or electronic authorizations for testing must include the patient's sex and age or date of birth as specified now at § 493.1241. We expect a negligible increase in burden or cost because the patient's age or date of birth was required for Pap smears, formerly at § 493.1105(e), and most laboratories are already obtaining the patient's gender, since it is frequently necessary for appropriate test interpretation (as required formerly at § 493.1105(f)). The number of laboratories that have not been requesting the patient's gender and age or date of birth is unknown.

• The laboratory must use a control system capable of detecting reaction inhibition when performing molecular amplification procedures in which inhibition is a significant source of false negative results. This is a recommended guideline for good laboratory practice by several laboratory professional organizations and is now specified at § 493.1256(d)(3)(v). While we are unable to estimate the incidence of reaction inhibition or number of laboratories performing molecular amplification procedures without following the recommended guideline, we expect the number to be small and any increase in burden and/or cost with meeting this new requirement negligible.

• The laboratory must check immunohistochemical stains for positive and negative reactivity each time of use. Although this is an increase from the requirement (formerly at § 493.1259, now at § 493.1273(a)) to check special stains for positive reactivity, we cannot estimate the laboratory impact because we do not know the number of laboratories that perform immunohistochemical stains or how often the staining is performed. We expect this change to affect a small number of laboratories, and the increase in burden and costs will be small.

• In the specialty of clinical cytogenetics, sex determination must be performed by full chromosome analysis. Formerly, in clinical cytogenetics at § 493.1267(a) (now at § 493.1276(c)), full chromosome analysis was only required as a confirmatory test when the laboratory obtained atypical results on X and Y chromatin counts. Several commenters stated that due to the frequency of mosaicism in individuals with sex chromosome anueploidy, Barr body and ''Y'' body analysis is no longer considered the standard of practice for sex determination and should be eliminated from the cytogenetics laboratory test menu. Several laboratory professional organizations consider sex determination by full chromosome analysis the standard for good laboratory practice; therefore, we added this requirement. Although we are unable to estimate the number of cytogenetics laboratories that perform sex determination other than by full chromosome analysis, we expect the number to be small and any increase in burden or cost with meeting this requirement negligible.

• The requirements for the test report (formerly at § 493.1109, now at § 493.1291) must include the patient's name and identification number, or unique patient identifier and identification number; the test report date; and if appropriate, the specimen source. These are standard practices in most laboratories and the impact on burden or cost is expected to be minor.

In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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List of Subjects in 42 FR Part 493

Grant programs—health, Health facilities, Incorporation by Reference, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV part 493 as set forth below:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), and the sentence following 1395x(s)(11) through 1395x(s)(16)).

Subpart A—General Provisions

2. In § 493.2, the introductory text is republished, and the following definitions are added in alphabetical order to read as follows:

§ 493.2 Definitions

As used in this part, unless the context indicates otherwise—

* * * * *

Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

* * * * *

FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

* * * * *

Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

* * * * *

Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

* * * * *

§ 493.3 [Amended]

3. Amend § 493.3, as follows:

a. In paragraph(b)(3), remove the words ''National Institutes on Drug Abuse (NIDA)'' and add, in their place, the words ''Substance Abuse and Mental Health Services Administration (SAMHSA)''.

b. In paragraph (b)(3), remove the word ''NIDA'' and add, in its place, the word ''SAMHSA''.

§ 493.20 [Amended]

3a. Amend § 493.20, as follows:

a. In paragraph (b), remove the reference to ''subpart P''.

b. In paragraph (b), remove the cross reference to ''§ 493.1777'' and add, in its place ''§§ 493.1773 and 493.1777''.

c. In paragraph (c), remove the cross reference to ''§§ 493.15(e) and 493.1775'' and add, in its place, ''§§ 493.15(e), 493.1773, and 493.1775''.

§ 493.25 [Amended]

4. Amend § 493.25 as follows:

a. In paragraph (b), remove the reference to ''subpart P''.

b. In paragraph (c), remove the reference to ''subpart P''.

c. In paragraph (c), remove ''§ 493.1777'' and add, in its place, ''§§ 493.1773 and 493.1777''.

d. In paragraph (d), remove the reference to ''subpart P''.

e. In paragraph (d), remove the cross reference to ''§§ 493.15(e) and 493.1775'' and add, in its place, ''§§ 493.15(e), 493.1773, and 493.1775''.

Subpart C—Registration Certificate, Certificate for Provider-Performed Microscopy Procedures, and Certificate of Compliance

§ 493.43 [Amended]

6. In § 493.43(a), remove the words ''tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests,'' and add, in their place, the words ''nonwaived testing''.

§ 493.45 [Amended]

7. In § 493.45(c)(3), remove the reference to ''subpart P''.

§ 493.47 [Amended]

8. Amend § 493.47 as follows:

a. In paragraph (c)(2), remove the reference to ''subpart P''.

b. In paragraph (c)(3), remove the cross reference to ''§ 493.1776'' and add, in its place, ''§§ 493.1773 and 493.1775''.

§ 493.49 [Amended]

9. In § 493.49(a)(3), remove the reference to ''subpart P''.

Subpart F—General Administration

§ 493.643 [Amended]

10. In § 493.643(c)(3)(ix), add the word ''Clinical'' before the word ''Cytogenetics''.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

11. Revise the heading of Subpart H to read as set forth above.

§ 493.801 [Amended]

12. In § 493.801(a)(2)(ii), remove the cross reference to ''§ 493.1709'' and add, in its place, ''§ 493.1236(c)(1)''.

§ 493.803 [Amended]

13. In § 493.803(a), remove the words ''tests of moderate complexity (including the subcategory) and/or high complexity'' and add, in their place, the words ''nonwaived testing''.

§ 493.807 [Amended]

14. Revise the heading of §493.807 to read as follows:

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

15. Revise the heading of subpart I to read as set forth above.

§§ 493.911, 493.913, 493.915, 493.917, 493.919, 493.923, 493.927, 493.931, 493.933, 493.937, and 493.941 [Amended]

16. In §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1), remove ''90 percent'' and add, in its place, ''80 percent'' wherever it appears.

§ 493.945 [Amended]

17. In § 493.945(a)(1), remove ''§ 493.1257'' and add, in its place,

''§§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2)''.

18. Subpart J, consisting of §§ 493.1100 through 493.1105, and subpart K, consisting of §§ 493.1200 through 493.1299, are revised to read as follows:

Subpart J—Facility Administration for Nonwaived Testing

Sec.
493.1100 Condition: Facility administration.
493.1101 Standard: Facilities.
493.1103 Standard: Requirements for transfusion services.
493.1105 Standard: Retention requirements.

Subpart K—Quality Systems for Nonwaived Testing

493.1200 Introduction.
493.1201 Condition: Bacteriology.
493.1202 Condition: Mycobacteriology.
493.1203 Condition: Mycology.
493.1204 Condition: Parasitology.
493.1205 Condition: Virology.
493.1207 Condition: Syphilis serology.
493.1208 Condition: General immunology.
493.1210 Condition: Routine chemistry.
493.1211 Condition: Urinalysis.
493.1212 Condition: Endocrinology.
493.1213 Condition: Toxicology.
493.1215 Condition: Hematology.
493.1217 Condition: Immunohematology.
493.1219 Condition: Histopathology.
493.1220 Condition: Oral pathology.
493.1221 Condition: Cytology.
493.1125 Condition: Clinical cytogenetics.
493.1226 Condition: Radiobioassay.
493.1227 Condition: Histocompatibility.

General Laboratory Systems

493.1230 Condition: General laboratory systems.
493.1231 Standard: Confidentiality of patient information.
493.1232 Standard: Specimen identification and integrity.
493.1233 Standard: Complaint investigations.
493.1234 Standard: Communications.
493.1235 Standard: Personnel competency assessment policies.
493.1236 Standard: Evaluation of proficiency testing performance.
493.1239 Standard: General laboratory systems assessment.

Preanalytic Systems

493.1240 Condition: Preanalytic systems.
493.1241 Standard: Test request.
493.1242 Standard: Specimen submission, handling, and referral.
493.1249 Standard: Preanalytic systems assessment.

Analytic Systems

493.1250 Condition: Analytic systems.
493.1251 Standard: Procedure manual.
493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.
493.1253 Standard: Establishment and verification of performance specifications.
493.1254 Standard: Maintenance and function checks.
493.1255 Standard: Calibration and calibration verification procedures.
493.1256 Standard: Control procedures.
493.1261 Standard: Bacteriology.
493.1262 Standard: Mycobacteriology.
493.1263 Standard: Mycology.
493.1264 Standard: Parasitology.
493.1265 Standard: Virology.
493.1267 Standard: Routine chemistry.
493.1269 Standard: Hematology.
493.1271 Standard: Immunohematology.
493.1273 Standard: Histopathology.
493.1274 Standard: Cytology.
493.1276 Standard: Clinical cytogenetics.
493.1278 Standard: Histocompatibility.
493.1281 Standard: Comparison of test results.
493.1282 Standard: Corrective actions.
493.1283 Standard: Test records.
493.1189 Standard: Analytic systems assessment.

Postanalytic Systems

493.1290 Condition: Postanalytic systems.
493.1291 Standard: Test report.
493.1299 Standard: Postanalytic systems assessment.

Subpart J—Facility Administration for Nonwaived Testing

§ 493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§ 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

§ 493.1101 Standard: Facilities.

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

§ 493.1103 Standard: Requirements for transfusion services.

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

(a) *Arrangement for services.* The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

(b) *Provision of testing.* The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(c) *Blood and blood products storage and distribution.* (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

(d) *Investigation of transfusion reactions.* The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

§ 493.1105 Standard: Retention requirements.

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

(1) *Test requisitions and authorizations.* Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

(2) *Test procedures.* Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

(3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, if applicable) and all analytic systems activities specified in §§ 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

(i) Records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(v), and (d).

(4) *Proficiency testing records.* Retain all proficiency testing records for at least 2 years.

(5) *Laboratory quality systems assessment records.* Retain all laboratory quality systems assessment records for at least 2 years.

(6) *Test reports.* Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

(i) Immunohematology reports as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), and (d).

(ii) Pathology test reports for at least 10 years after the date of reporting.

(7) *Slide, block, and tissue retention*—

(i) *Slides.*

(A) Retain cytology slide preparations for at least 5 years from the date of examination (see § 493.1274(f) for proficiency testing exception).

(B) Retain histopathology slides for at least 10 years from the date of examination.

(ii) *Blocks.* Retain pathology specimen blocks for at least 2 years from the date of examination.

(iii) *Tissue.* Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are maintained and available for the time frames specified in this section.

Subpart K—Quality Systems for Nonwaived Testing

§ 493.1200 Introduction.

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor quality systems for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) Each of the laboratory's quality systems must include an assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality systems are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

§ 493.1201 Condition: Bacteriology.

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1261, and §§ 493.1281 through 493.1299.

§ 493.1202 Condition: Mycobacteriology.

If the laboratory provides services in the subspecialty of Mycobacteriology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1262, and §§ 493.1281 through 493.1299.

§ 493.1203 Condition: Mycology.

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1263, and §§ 493.1281 through 493.1299.

§ 493.1204 Condition: Parasitology.

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1264, and §§ 493.1281 through 493.1299.

§ 493.1205 Condition: Virology.

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1265, and §§ 493.1281 through 493.1299.

§ 493.1207 Condition: Syphilis serology.

If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1208 Condition: General immunology.

If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 93.1281 through 493.1299.

§ 493.1210 Condition: Routine chemistry.

If the laboratory provides services in the subspecialty of Routine chemistry, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1267, and §§ 493.1281 through 493.1299.

§ 493.1211 Condition: Urinalysis.

If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1212 Condition: Endocrinology.

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1213 Condition: Toxicology.

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1215 Condition: Hematology.

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1269, and §§ 493.1281 through 493.1299.

§ 493.1217 Condition: Immunohematology.

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1271, and §§ 493.1281 through 493.1299.

§ 493.1219 Condition: Histopathology.

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1273, and §§ 493.1281 through 493.1299.

§ 493.1220 Condition: Oral pathology.

If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1221 Condition: Cytology.

If the laboratory provides services in the subspecialty of Cytology, the

laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1274, and §§ 493.1281 through 493.1299.

§ 493.1225 Condition: Clinical cytogenetics.

If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1276, and §§ 493.1281 through 493.1299.

§ 493.1226 Condition: Radiobioassay.

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1227 Condition: Histocompatibility.

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1278, and §§ 493.1281 through 493.1299.

General Laboratory Systems

§ 493.1230 Condition: General laboratory systems.

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§ 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as specified in § 493.1239 for each specialty and subspecialty of testing performed.

§ 493.1231 Standard: Confidentiality of patient information.

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

§ 493.1232 Standard: Specimen identification and integrity.

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

§ 493.1233 Standard: Complaint investigations.

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

§ 493.1234 Standard: Communications.

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized individual who orders or receives test results.

§ 493.1235 Standard: Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

§ 493.1236 Standard: Evaluation of proficiency testing performance.

(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

(b) The laboratory must verify the accuracy of the following:

(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).

(c) At least twice annually, the laboratory must verify the accuracy of the following:

(1) Any test or procedure it performs that is not included in subpart I of this part.

(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

(d) All proficiency testing evaluation and verification activities must be documented.

§ 493.1239 Standard: General laboratory systems assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system requirements specified at §§ 493.1231 through 493.1236.

(b) The general laboratory systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems assessment reviews with appropriate staff.

(c) The laboratory must document all general laboratory systems assessment activities.

Preanalytic Systems

§ 493.1240 Condition: Preanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in §§ 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in § 493.1249 for each specialty and subspecialty of testing performed.

§ 493.1241 Standard: Test request.

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

(c) The laboratory must ensure the test requisition solicits the following information:

(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

(2) The patient's name or unique patient identifier.

(3) The sex and age or date of birth of the patient.

(4) The test(s) to be performed.

(5) The source of the specimen, when appropriate.

(6) The date and, if appropriate, time of specimen collection.

(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

§ 493.1242 Standard: Specimen submission, handling, and referral.

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(1) Patient preparation.

(2) Specimen collection.

(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

(4) Specimen storage and preservation.

(5) Conditions for specimen transportation.

(6) Specimen processing.

(7) Specimen acceptability and rejection.

(8) Specimen referral.

(b) The laboratory must document the date and time it receives a specimen.

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

§ 493.1249 Standard: Preanalytic systems assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems assessment reviews with appropriate staff.

(c) The laboratory must document all preanalytic systems assessment activities.

Analytic Systems

§ 493.1250 Condition: Analytic systems.

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§ 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in § 493.1289 for each specialty and subspecialty of testing performed.

§ 493.1251 Standard: Procedure manual.

(a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include the following when applicable to the test procedure:

(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in § 493.1242.

(2) Microscopic examination, including the detection of inadequately prepared slides.

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(5) Calibration and calibration verification procedures.

(6) The reportable range for test results for the test system as established or verified in § 493.1253.

(7) Control procedures.

(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

(9) Limitations in the test methodology, including interfering substances.

(10) Reference intervals (normal values).

(11) Imminently life-threatening test results or panic or alert values.

(12) Pertinent literature references.

(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in § 493.1105(a)(2).

§ 493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under § 493.1253.

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(1) Water quality.

(2) Temperature.

(3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

(4) Other pertinent information required for proper use.

(d) Reagents, solutions, culture media, control materials, calibration materials,

and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

§ 493.1253 Standard: Establishment and verification of performance specifications.

(a) *Applicability.* Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

(b)(1) *Verification of performance specifications.* Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

(A) Accuracy.

(B) Precision.

(C) Reportable range of test results for the test system.

(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

(2) *Establishment of performance specifications.* Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures, Gram stain, or potassium hydroxide preparations), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

(i) Accuracy.

(ii) Precision.

(iii) Analytical sensitivity.

(iv) Analytical specificity to include interfering substances.

(v) Reportable range of test results for the test system.

(vi) Reference intervals (normal values).

(vii) Any other performance characteristic required for test performance.

(3) *Determination of calibration and control procedures.* The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

(c) *Documentation.* The laboratory must document all activities specified in this section.

§ 493.1254 Standard: Maintenance and function checks.

(a) *Unmodified manufacturer's equipment, instruments, or test systems.* The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

(b) *Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer.* The laboratory must do the following:

(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

§ 493.1255 Standard: Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:

(a) Perform and document calibration procedures—

(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(2) Using the criteria verified or established by the laboratory as specified in § 493.1253(b)(3)—

(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

(b) Perform and document calibration verification procedures—

(1) Following the manufacturer's calibration verification instructions;

(2) Using the criteria verified or established by the laboratory under § 493.1253(b)(3)—

(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(3) At least once every 6 months and whenever any of the following occur:

(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

§ 493.1256 Standard: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process.

(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified

or established by the laboratory as specified in § 493.1253(b)(3).

(c) The control procedures must—

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must—

(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§ 493.1261 through 493.1278.

(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(3) At least once each day patient specimens are assayed or examined perform the following for—

(i) Each quantitative procedure, include two control materials of different concentrations;

(ii) Each qualitative procedure, include a negative and positive control material;

(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and

(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

(4) For thin layer chromatography—

(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and

(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.

(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

(7) Over time, rotate control material testing among all operators who perform the test.

(8) Test control materials in the same manner as patient specimens.

(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

(10) Establish or verify the criteria for acceptability of all control materials.

(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

(e) For reagent, media, and supply checks, the laboratory must do the following:

(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

(4) Before, or concurrent with the initial use—

(i) Check each batch of media for sterility if sterility is required for testing;

(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

(g) The laboratory must document all control procedures performed.

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

§ 493.1261 Standard: Bacteriology.

(a) The laboratory must check the following for positive and negative reactivity using control organisms:

(1) Each day of use for beta-lactamase methods other than Cefinase™.

(2) Each week of use for Gram stains.

(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1262 Standard: Mycobacteriology.

(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

(b) For antimycobacterial susceptibility tests, the laboratory must

check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1263 Standard: Mycology.

(a) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).

(b) For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1264 Standard: Parasitology.

(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1265 Standard: Virology.

(a) When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.

(b) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1267 Standard: Routine chemistry.

For blood gas analyses, the laboratory must perform the following:

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

(d) Document all control procedures performed, as specified in this section.

§ 493.1269 Standard: Hematology.

(a) For manual cell counts performed using a hemocytometer—

(1) One control material must be tested each 8 hours of operation; and

(2) Patient specimens and control materials must be tested in duplicate.

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

(c) For manual coagulation tests—

(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(2) Patient specimens and control materials must be tested in duplicate.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1271 Standard: Immunohematology.

(a) *Patient testing.* (1) The laboratory must perform ABO grouping, D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(3) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

(b) *Immunohematological testing and distribution of blood and blood products.* Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

(c) *Blood and blood products storage.* Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(2) Inspections of the alarm system must be documented.

(d) *Retention of samples of transfused blood.* According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

(e) *Investigation of transfusion reactions.* (1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

(f) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1273 Standard: Histopathology.

(a) Fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in § 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an

individual qualified under §§ 493.1449(b), (l), or (m).

(c) An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

(f) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1274 Standard: Cytology.

(a) *Cytology slide examination site.* All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) *Staining.* The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

(1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.

(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

(c) *Control procedures.* The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:

(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§ 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).

(i) The review must be performed by an individual who meets one of the following qualifications:

(A) A technical supervisor qualified under §§ 493.1449(b) or (k).

(B) A cytology general supervisor qualified under § 493.1469.

(C) A cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.

(iii) The review of those cases selected must be completed before reporting patient results.

(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) Records of initial examinations and all rescreening results must be documented.

(5) An annual statistical laboratory evaluation of the number of—

(i) Cytology cases examined;

(ii) Specimens processed by specimen type;

(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(v) Gynecologic cases where cytology and histology are discrepant; and

(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation and, if appropriate, corrective actions taken.

(d) *Workload limits.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

(i) The workload limit is based on the individual's performance using evaluations of the following:

(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section.

(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition—

(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula—

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

is used to determine maximum slide volume to be examined;

(iii) Nongynecologic slide preparation made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

(3) The laboratory must maintain records of the total number of slides examined by each individual during

each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

(4) Records are available to document the workload limit for each individual.

(e) *Slide examination and reporting.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(i) Squamous cell.

(A) Atypical squamous cells of undetermined significance (ASC–US) or cannot exclude HSIL (ASC–H).

(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).

(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.

(D) Squamous cell carcinoma.

(ii) Glandular cell.

(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).

(B) Atypical cells favor neoplastic (endocervical or glandular).

(C) Endocervical adenocarcinoma in situ.

(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(iii) Other malignant neoplasms.

(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

(5) The report contains narrative descriptive nomenclature for all results.

(6) Corrected reports issued by the laboratory indicate the basis for correction.

(f) *Record and slide retention.* (1) The laboratory must retain all records and slide preparations as specified in § 493.1105.

(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

(4) All slides must be retrievable upon request.

(g) *Automated and semi-automated screening devices.* When performing evaluations using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

(h) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1276 Standard: Clinical cytogenetics.

(a) The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs.

(b) The laboratory must have records that document the following:

(1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding.

(2) The resolution is appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided to the laboratory.

(3) An adequate number of karyotypes are prepared for each patient.

(c) Determination of sex must be performed by full chromosome analysis.

(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System of Cytogenetic Nomenclature.

(e) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1278 Standard: Histocompatibility.

(a) *General.* The laboratory must meet the following requirements:

(1) An audible alarm system must be used to monitor the storage temperature of specimens (donor and recipient) and reagents. The laboratory must have an emergency plan for alternate storage.

(2) All patient specimens must be easily retrievable.

(3) Reagent typing sera inventory prepared in-house must indicate source, bleeding date and identification number, reagent specificity, and volume remaining.

(4) If the laboratory uses immunologic reagents (for example, antibodies, antibody-coated particles, or complement) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

(5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b) *HLA typing.* The laboratory must do the following:

(1) Use a technique(s) that is established to optimally define, as applicable, HLA Class I and II specificities.

(2) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection.

(3) HLA type cells from organ donors referred to the laboratory.

(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.

(5) Have available and follow written criteria for the following:

(i) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

(ii) Selecting typing reagents, whether prepared in-house or commercially.

(iii) Ensuring that reagents used for typing are adequate to define all HLA–A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available.

(iv) The assignment of HLA antigens.

(v) When antigen redefinition and retyping are required.

(6) Check each HLA typing by testing, at a minimum the following:

(i) A positive control material.

(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of

incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.

(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

(c) *Disease-associated studies.* The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(d) *Antibody Screening.* The laboratory must do the following:

(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

(6) Check each antibody screening by testing, at a minimum the following:

(i) A positive control material containing antibodies of the appropriate isotype for the assay.

(ii) A negative control material.

(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

(e) *Crossmatching.* The laboratory must do the following:

(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

(2) Have available and follow written criteria for the following:

(i) Selecting appropriate patient serum samples for crossmatching.

(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(f) *Transplantation.* Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:

(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable—

(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;

(ii) Testing protocols for patients at high risk for allograft rejection; and

(iIi) The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

(g) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1281 Standard: Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(1) Patient age.

(2) Sex.

(3) Diagnosis or pertinent clinical data.

(4) Distribution of patient test results.

(5) Relationship with other test parameters.

(c) The laboratory must document all test result comparison activities.

§ 493.1282 Standard: Corrective actions.

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in § 493.1253(b), which include but are not limited to—

(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and

(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

(3) The criteria for proper storage of reagents and specimens, as specified under § 493.1252(b), are not met.

§ 493.1283 Standard: Test records.

(a) The laboratory must maintain an information or record system that includes the following:

(1) The positive identification of the specimen.

(2) The date and time of specimen receipt into the laboratory.

(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(4) The records and dates of all specimen testing, including the identity

of the personnel who performed the test(s).

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

§ 493.1289 Standard: Analytic systems assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§ 493.1251 through 493.1283.

(b) The analytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems assessment reviews with appropriate staff.

(c) The laboratory must document all analytic systems assessment activities.

Postanalytic Systems

§ 493.1290 Condition: Postanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in § 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in § 493.1299 for each specialty and subspecialty of testing performed.

§ 493.1291 Standard: Test report.

(a) The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

(1) Results reported from calculated data.

(2) Results and patient-specific data electronically reported to network or interfaced systems.

(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number, or an unique patient identifier and identification number.

(2) The name and address of the laboratory location where the test was performed.

(3) The test report date.

(4) The test performed.

(5) Specimen source, when appropriate.

(6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent ''reference intervals'' or ''normal'' values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in § 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(f) Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition, or panic or alert values.

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

(i) If a laboratory refers patient specimens for testing—

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

(3) Maintain duplicates of the original report, as well as the corrected report.

§ 493.1299 Standard: Postanalytic systems assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in § 493.1291.

(b) The postanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems assessment reviews with appropriate staff.

(c) The laboratory must document all postanalytic systems assessment activities.

Subpart M—Personnel for Nonwaived Testing

19. Revise the heading of Subpart M to read as set forth above.

§ 493.1359 [Amended]

20. § 493.1359(b)(2), remove the reference to ''subpart P''.

§ 493.1407 [Amended]

21. In § 493.1407(e)(5), remove the word ''assurance'' and, add in its place, the word ''assessment''.

22. In § 493.1443, paragraph (b) introductory text is republished, and paragraph (b)(3) is revised to read as follows:

§ 493.1443 Standard: Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

* * * * *

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—

(i) Be certified and continue to be certified by a board approved by HHS; or

(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—

(A) Two years of laboratory training or experience, or both; and

(B) Two years of laboratory experience directing or supervising high complexity testing.

* * * * *

§ 493.1445 [Amended]

23. In § 493.1445(e)(5), remove the word ''assurance'' and add, in its place, the word ''assessment''.

§ 493.1451 [Amended]

24. In § 493.1451(c)(4), remove the cross reference to ''§ 493.1257(c)'' and add, in its place, ''§ 493.1274(d) and (e)''.

§ 493.1471 and § 493.1485 [Amended]

25. In §§ 493.1471(b)(2) and 493.1485(a), remove the cross reference to ''§ 493.1257(d)'' and add, in its place, ''§ 493.1274(c)''.

Subpart P—[Reserved]

26. Subpart P consisting of §§ 493.1701 through 493.1721, is removed and reserved.

Subpart R—Enforcement Procedures

§ 493.1844 [Amended]

27. In § 493.1844(c)(1), remove the reference to ''subpart P''.

Subpart T—Consultations

§ 493.2001 [Amended]

28. Amend § 493.2001 as follows:

a. In paragraph (e)(1), remove the words ''tests and examinations of moderate complexity (including the subcategory) and high complexity'' and add, in their place, the words ''nonwaived testing''.

b. Revise paragraph (e)(4) to read as follows:

* * * * *

(e) * * *

(4) Facility administration and quality systems standards.

* * * * *

Dated: October 7, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 13, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–1230 Filed 1–23–03; 8:45 am]

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Federal Register

Friday,
January 24, 2003

Part IV

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Parts 2520, et al.

Final Rule Relating to Notice of Blackout Periods to Participants and Beneficiaries; Civil Penalties and Conforming Technical Changes on Civil Penalties Under ERISA; Final Rules

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2520

RIN 1210–AA90

Final Rule Relating to Notice of Blackout Periods to Participants and Beneficiaries

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Final rule.

SUMMARY: This document contains a final rule under new section 101(i) of the Employee Retirement Income Security Act of 1974 (the Act or ERISA). Section 101(i) of ERISA, which was enacted into law on July 30, 2002 as part of the Sarbanes-Oxley Act of 2002 (the SOA), provides that written notice is to be provided to affected participants and beneficiaries of individual account plans of any ''blackout period'' during which their right to direct or diversify investments, obtain a loan or obtain a distribution under the plan may be temporarily suspended. The final rules provide guidance to plan sponsors, administrators, participants and beneficiaries regarding the requirements for furnishing notices of blackout periods in individual account pension plans.

DATES: *Effective date:* This final rule is effective January 26, 2003. *Applicability date:* This final rule shall apply to blackout periods commencing on or after January 26, 2003.

FOR FURTHER INFORMATION CONTACT: Janet A. Walters, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor, Washington, DC 20210, (202) 693–8510 (not a toll free number).

SUPPLEMENTARY INFORMATION:

A. Background

The Sarbanes-Oxley Act of 2002 (the SOA), Pub. L. 107–204, was enacted on July 30, 2002. Section 306(b)(1) of the SOA amended section 101 of ERISA to add a new subsection (i), requiring that administrators of individual account plans provide notice to affected participants and beneficiaries in advance of the commencement of any blackout period. For purposes of this notice requirement, a blackout period generally includes any period during which the ability of participants or beneficiaries to direct or diversify assets credited to their accounts, to obtain loans from the plan or to obtain distributions from the plan will be temporarily suspended, limited or restricted. The most common reasons for imposition of a blackout period include changes in investment alternatives or recordkeepers, and corporate mergers, acquisitions, and spin-offs that impact the pension coverage of groups of participants.

ERISA section 101(i)(6) provides that the Secretary shall issue model notices that meet the requirements of subsection (i). A model notice is included as part of this final rule.

Section 306(b)(3) of the SOA amends ERISA section 502 to establish a new civil penalty applicable to a plan administrator's failure or refusal to provide the blackout notice required by section 101(i) of ERISA. Final rules implementing this civil penalty appear elsewhere in today's issue of the **Federal Register**.

On October 21, 2002, the Department published an interim final rule, including a model notice, in the **Federal Register** (67 FR 64766) for public comment. The Department received 14 comment letters in response to its request for comments. Set forth below is an overview of the final rule and the public comments submitted on the interim final rule.

B. Overview of Final Rule and Comments

1. General

Paragraph (a) of § 2520.101–3 of the final rule, like the interim final rule, describes the general requirement of section 101(i) of ERISA that administrators of certain individual account plans provide notice of blackout periods to participants and beneficiaries whose rights under the plan will be temporarily suspended, limited or restricted by a blackout period (the ''affected participants and beneficiaries''), as well as to issuers of employer securities held by the plan.

2. Content of the Notice § 2520.101–3(b)(1)

Paragraph (b)(1) of § 2520.101–3 of the final rule, like the interim final rule, sets forth the content requirements for notices to be furnished to affected participants and beneficiaries. Paragraph (b)(1) provides that the notices shall be written in a manner calculated to be understood by the average plan participant and sets forth the specific content requirements applicable to the notices. The content requirements of the regulation essentially track the requirements of section 101(i)(2)(A) of the Act. Paragraph (b)(1)(ii), like the interim final rule, provides that the notice must include a description of the rights otherwise available under the plan to affected participants and beneficiaries that will be temporarily suspended during the blackout period, in addition to the identification of the investments subject to the blackout period.

Paragraph (b)(1)(iii) requires that the notice set forth information concerning the length of the blackout period. The interim final rule required that the notice set forth the expected beginning date and ending date of the blackout period. A number of commenters expressed concern about the difficulty of projecting thirty or more days in advance the specific beginning and ending dates of a blackout period, noting that a wide range of events (*e.g.,* problems with plan records or recordkeeper, extensive document reviews and data reconciliation, required modifications to systems and software) that may affect actual dates. As a result of such events, commenters state that specific dates are likely to be missed, and updated notices with their attendant costs would have to be furnished. In an effort to avoid this problem, sponsors and fiduciaries may be encouraged to establish unnecessarily long blackout periods, thereby depriving participants and beneficiaries of their right to exercise their affected rights for a longer period of time. To address this problem, commenters suggested that the notice be permitted to identify a range of dates during which the blackout period might begin and end. The suggestions included: A range of plus or minus 3 business days, 5 days, 7 days; identification of the ''week of ____'' during which blackout period might begin and end; and a description of events that might result in the end of the blackout period. Some commenters suggested that where a range of dates is provided, participants also would be furnished a toll-free number or web site that would enable them to determine the specific date on which the blackout period began and ended. One commenter suggested that where other than a specific date is given in the notice, a subsequent less formal notice should be provided to inform the participants of the beginning or ending of the blackout.

The Department continues to believe that it is important that participants and beneficiaries have sufficiently specific information to factor the duration of the blackout into their pre-blackout period investment and other decisions and to apprise participants and beneficiaries as to when they will be able to recommence exercising their rights

under the plan. However, the Department also recognizes the difficulty of projecting specific beginning and ending dates thirty or more days in advance of a blackout period and that there may be significant costs to providing updated notices, most or all of which will be charged to the individual accounts of the plans' participants.

The Department is persuaded that allowing a limited range of dates for purposes of defining the beginning and ending dates for a blackout period in the required notice will serve to provide participants and beneficiaries with adequate pre-blackout period planning information, provided that they also have access during such dates to information to determine whether the blackout period has begun or ended. In addition, the Department is persuaded that such an approach will help to reduce plan administrative costs that might otherwise result from multiple notices; thereby preserving assets for the retirement security of plan participants and beneficiaries.

As amended, paragraph (b)(1)(iii) permits the notice to describe the length of the blackout period by reference to either: (A) The expected beginning date and ending date of the blackout period; or (B) the calendar week during which the blackout period is expected to begin and end, provided that during such weeks information as to whether the blackout period has begun or ended is readily available, without charge, to affected participants and beneficiaries, such as via a toll-free number or access to a specific web site, and the notice describes how to access the information.

The Department decided to permit reference to ''the calendar week'' because, unlike 3 or 5 or 7 day, plus or minus, ranges, it provides both the flexibility for plan administrators and a clearer degree of certainty for plan participants and beneficiaries. As reflected in the description of the change, specific information must be readily available, without charge, to participants and beneficiaries during the identified ''week of____'' as to whether the blackout has begun or ended. The regulation provides examples as how this requirement can be satisfied, namely via a toll-free number or access to a specific web site. ''Calendar week'' is defined in the regulation, at paragraph (d)(5) to mean ''a seven day period beginning on Sunday and ending on Saturday.''

For example, in the case of a plan that expects to have a four week blackout period beginning February 10, 2003 and ending March 7, 2003, the notice of the blackout period could, in accordance with the final rule, indicate that the blackout period for the plan will begin ''the week of February 9, 2003 and end the week of March 2, 2003.'' The notice also would have to indicate the means by which participants and beneficiaries can determine, during the weeks of February 9 and March 2, whether the blackout period has begun or ended. It is the view of the Department that, given the benefits to affected participants and beneficiaries of specific beginning and ending dates, the regulation should not be construed to preclude the use of a specific beginning date and a ''week of____'' ending date, or the converse.

The Department notes that, in the case of a plan that permits participants to exercise their rights up to the commencement of the blackout period (*e.g.*, as might be the case where participants are permitted to trade daily), the timing of the advance notice must be calculated back from the earliest possible beginning date identified in the notice. For example, in the case of a plan identifying the blackout period as beginning the ''week of February 9,'' February 9 will be the beginning of the blackout period for purposes of applying the timing rule of the regulation.

The Department has modified paragraph 3 of the model notice (at paragraph (e)(2) of the final rule) to reflect the availability of alternative approaches to describing the length of the blackout period.

Finally, some commenters noted that blackout periods often affect certain rights longer than others (*e.g.*, a 20 day blackout for loans and a 10 day blackout for distributions and investment changes) and requested clarification that one notice describing the different blackout periods is permitted under the regulation. There is nothing in the regulation that is intended to limit the ability of plan administrators to use a single notice to describe different blackout periods, provided that the advance notice and other requirements of the regulation can be satisfied with respect to such blackout periods.

Paragraph (b)(1)(iv) of the final rule, like the interim final rule, requires the inclusion of a statement advising participants and beneficiaries to review their current investments in light of their inability to direct or diversify their assets during the blackout period and provides that use of the advisory statement contained in paragraph 4 of the model notice (at paragraph (e)(2)) will satisfy this content requirement for the notice.

With regard to paragraph 4 of the model, commenters requested a clarification that the sentences relating to the risks of investments in individual securities are not required in those instances where a plan does not permit investments in such securities. Paragraph 4 of the model in the final rule, therefore, has been modified to clarify that the last two sentences are required only where the plan permits investments in individual securities.

Section 101(i)(2)(A)(v) of the Act provides that the notice shall contain ''such other matters as the Secretary may require by regulation.'' In this regard, the Department added, for purposes of the interim final rule, two informational items.

First, given the importance of adequate advance notice of blackout periods to plan participants and beneficiaries, paragraph (b)(1)(v) of the interim final rule provided that, where notices are furnished less than 30 days in advance of the last date on which affected participants and beneficiaries could exercise affected rights immediately before the commencement of the blackout period, the notice must contain a general statement concerning the Federal law requirement of 30 days advance notice and an explanation as to why such notice could not be furnished. The requirement for a general statement in paragraph (b)(1)(v)(A) would be satisfied if the notice contains the general statement appearing in paragraph 5(A) of the model notice (at paragraph (e)(2)). Paragraph (b)(1)(v) would not apply to the exceptions in paragraph (b)(2)(ii)(C) involving blackout periods in connection with mergers, acquisitions, divestitures, or similar transactions inasmuch as notices of such blackout periods are required to be furnished as soon as reasonably possible. (See ERISA section 101(i)(3).) The Department received no comments on paragraph (b)(1)(v) and is adopting the provision without change in the final rule.

Second, the Department had determined that the notice should contain the name, address and telephone number of a person who can answer questions concerning the blackout period. Specifically, paragraph (b)(1)(vi) provided that the notice must contain the name, address and telephone number of the plan administrator or other person responsible for answering questions regarding the blackout period. The Department received one comment on this provision requesting a clarification that the contact person is not required to be an individual and could be the department employing the individual who would be answering questions (such as the benefits department). The regulation is not intended to require the

identification of a specific person. Rather, the regulation is intended to require the identification of a sufficiently specific source for answering questions concerning the blackout period that participants and beneficiaries will not be confused as to whom their questions should be addressed. The Department has modified paragraph (b)(1)(vi) of the final rule and paragraph 6 of the model notice (at paragraph (e)(2) of the final rule) by substituting ''contact'' for ''person'' to clarify this matter.

Finally, two commenters requested a clarification that notice of blackout periods may be furnished with other information, such as information relating to the change in service providers. There is nothing in the regulation that is intended to preclude blackout notice information from being furnished with other plan information, including benefit statements. However, given the importance of the blackout notice information to participants and beneficiaries, plan administrators should take steps to ensure that the blackout notice information is prominently identified in the furnished materials.

3. Timing of the Notice § 2520.101–3(b)(2)

Paragraph (b)(2) of the final rule, like the interim final rule, describes the timing requirements applicable to furnishing the notice to affected participants and beneficiaries. Paragraph (b)(2)(i) of the interim final rule provided that notice shall be furnished at least 30 days, but not more than 60 days, in advance of the last date on which affected participants and beneficiaries could exercise their affected rights immediately before the commencement of any blackout period. Some commenters indicated that the 30 day window created by the regulation within which to provide notices to affected participants and beneficiaries was not sufficient to prepare and furnish notices and suggested that the regulation extend the 60 day maximum period for furnishing advance notice to 90 days. One commenter suggested changing the minimum notice requirement to 45 days and the maximum period to 90 days, while another commenter suggested changing the minimum requirement to 60 days and the maximum requirement to 90 days to enable furnishing of the notice with quarterly benefit statements. After careful consideration of the comments on this provision, the Department has determined to retain the provision of the interim final rule without change.

The Department continues to believe that the 30 day minimum and 60 day maximum advance notice requirements of the interim final rule serve to ensure that affected participants and beneficiaries have sufficiently timely notice to enable them to both to consider the effects of the blackout period on their investments and financial plans and to take action, if appropriate, in anticipation of the blackout period. The 30-day minimum notice requirement is based on the statutory standard set forth in section 101(i)(2)(B) of ERISA. The 60-day maximum period is intended to ensure that notice is not furnished so far in advance of the commencement date so as to undermine the importance of the notice to affected participants and beneficiaries. The Department is concerned that if the only blackout notice is furnished 90 days in advance, many participants and beneficiaries would be inclined to defer consideration of the effects of the period on their individual accounts and some would, by virtue of the passage of time, forget altogether. As noted in the preamble to the interim final rule, there is nothing in the regulation that precludes an administrator from supplementing the requirements of the regulation, by furnishing earlier or more frequent notices than that required by regulation, provided that at least one notice is provided to participants and beneficiaries that complies with the timing and content of the rule. The Department also notes that, in most instances, plan administrators will have the flexibility to determine a beginning date for the blackout period that would permit timely notification of the blackout period to be made with the quarterly benefit statements furnished to affected participants and beneficiaries.

Like the interim final rule, the final rule requires that the notice periods be counted back from the last date on which the participant or beneficiary could exercise the affected rights immediately before the commencement of the blackout period. One commenter requested a clarification that the time period must take into account implementation of the exercised rights of the participant or beneficiary. The point of the advance notice is to enable participants and beneficiaries to take action in anticipation of a blackout period. Accordingly, merely affording participants or beneficiaries the opportunity to give investment instruction, or request a loan, or request a distribution without the ability to have such instruction or request implemented prior to the blackout period would be contrary to both the regulation and the statute. Therefore, plan administrators must take into account plan requirements, procedures and other factors that may affect implementation of participant or beneficiary instructions or requests in determining the last date on which participants and beneficiaries could exercise the affected rights before the commencement of the blackout period.

The timing rules are exemplified by the following. In the case of an individual account plan that provides for daily trading, the 30-day period would be counted back from the date immediately preceding the commencement of a blackout period affecting the right to trade. In the case of a plan that permits participants to direct their investments during the first fifteen days of each month, if a plan administrator determines that in order to change recordkeepers, participant direction of their investments will have to be suspended from the 1st to the 15th of May. If the 30-day notice period were counted from the date immediately preceding the commencement of the blackout period, notice could be provided on April 1st, thereby affording participants only 15 days (April 1st–15th) to consider and take action in anticipation of the blackout period. Under the regulation, notice is required to be furnished at least 30 days in advance of the last date on which participants could exercise the affected rights immediately before the commencement of the blackout period. In the immediate example, the last date on which participants could take action in anticipation of the blackout period would be April 15th; accordingly notice would have to be provided to participants not later than March 16th.

As with the interim final rule, all references in the regulation to ''days'' are references to calendar days, not business days, unless specifically noted otherwise.

Like the interim final rule, the final rule, at paragraph (b)(2)(ii)(A) and (B), sets forth two circumstances under which the 30-day advance notice requirement does not apply. The first circumstance is where a deferral of the blackout period would result in a violation of the exclusive purpose and prudence requirements of section 404(a)(1)(A) and (B) of the Act. For example, the ABC Company has announced that it is filing Chapter 11 bankruptcy. The ABC company's 401(k) plan has ABC common stock as one of its investment options. F, the 401(k) plan fiduciary and administrator, determines that, given this event, it would be prudent to temporarily

suspend investments in the ABC company stock, effective immediately. In such a situation, F would not, pursuant to § 2520.101–3(b)(2)(ii)(A), be required to give 30 days notice to the affected participants and beneficiaries, but would be required to notify them in writing as soon as possible of the blackout period.

The second circumstance under which the 30-day advance notice requirement does not apply is where commencement of the blackout period is due to events that were unforeseeable or circumstances that were beyond the control of the plan administrator. For example, the DEF company's profit-sharing plan's recordkeeper has informed plan administrator G that due to a major computer failure, the computer program for recording and processing loans and distributions from the plan has been incapacitated and that it will take approximately ten days to fix the system. In such a situation, G would not, pursuant to § 2520.101–3(b)(2)(ii)(B), be required to give 30 days' notice to the affected participants and beneficiaries of their temporary inability to receive loans and distributions from the plan, but would be required to notify them as soon as reasonably possible, unless G determines that such notice in advance of the termination of the blackout is impracticable. The Department anticipates that plan administrators will rely on this exception only in rare circumstances. In this regard, the Department notes that problems attendant to changes in recordkeepers will rarely be unforeseeable or beyond the control of the plan.

In both of the foregoing circumstances, a plan fiduciary, which can be the plan administrator, must make a written determination with respect to the exceptions to the 30-day advance notice requirement. Like the interim final rule, paragraph (b)(2)(iv) of the final rule requires that such determinations be dated and signed by a plan fiduciary.

Section 101(i)(3) of ERISA provides that in any case in which a blackout period applies only to one or more participants or beneficiaries in connection with a merger, acquisition, divestiture, or similar transaction involving the plan or plan sponsor and occurs solely in connection with becoming or ceasing to be a participant or beneficiary under the plan by reason of such merger, acquisition, divestiture, or similar transaction, the 30-day advance notice requirement shall be treated as met if the notice is furnished to such participants and beneficiaries to whom the blackout period applies as soon as reasonably practicable. Like paragraph (b)(2)(ii)(C) of the interim final rule, the final rule makes clear that notice to such participants and beneficiaries is an exception to the general rule that the 30-day notice be furnished to all affected participants and beneficiaries.

One commenter requested that the foregoing exception be extended to situations where the affected participants participate in both plans immediately before a plan merger and to situations where a plan merger or spin-off is not the result of a corporate merger, acquisition, divestiture or similar transaction. The Department believes that the exception at issue was intended to be applied to the narrow circumstances set forth in the statute. Moreover, the Department is not persuaded, on the basis of the information provided, that the burdens attendant to providing advance notice in the circumstances described by the commenter outweigh the benefits of the notice to affected participants and beneficiaries.

Paragraph (b)(2)(iii), like the interim final rule, provides that, in any case in which the 30-day advance notice rule is not required to be applied, the administrator is required to provide notice as soon as reasonably possible under the circumstances, unless such notice in advance of the termination of the blackout period is impracticable. If, therefore, a plan administrator or other fiduciary concludes under such circumstances that notice could not be furnished in sufficient time in advance of the termination of the blackout period to alert participants and beneficiaries of the termination date and resumption of plan rights, no notice would be required to be provided under this section. Such might be the case where the need for a blackout period is determined only a few days before the beginning of the blackout period and the blackout period is only a few days in duration.

One commenter requested as a clarification as to whether the ability to furnish sufficient advance notice is determined by reference to the ability of the plan administrator to provide such notice to all affected participants and beneficiaries. It is the view of the Department that paragraph (b)(2)(iii), as well as paragraph (b)(4) relating to changes in the length of the blackout period, require that an administrator take steps to furnish notice as soon as reasonably possible to all affected participants and beneficiaries and, therefore, to the extent that an administrator has the ability to furnish notice to some participants and beneficiaries earlier than other participants and beneficiaries, which may be the case where electronic disclosure is available, the administrator has an obligation to provide such notice, even though providing advance notice to other participants and beneficiaries (*e.g.,* by mail) may be impracticable.

Two commenters suggested that the timing rules should not apply with respect to new participants inasmuch as furnishing such notice as part of the plan enrollment package might be a problem because different third-party vendors may prepare the materials and, in addition, new participants are likely to have little, if any, funds that would be affected by the blackout period. The Department is not persuaded that administrative burdens and small account balances justify an exception to the timing rules for new plan participants. Accordingly, no exception from the timing requirements has been adopted for new participants. The Department notes, however, that if an employee becomes a participant after blackout notices have been furnished to the plan's participants and beneficiaries, the administrator would be required to furnish a notice to the newly eligible employee as soon as reasonably possible pursuant to the exception in § 2520.101–3(b)(2)(ii)(B).

4. Form and Manner of Furnishing Notice § 2520.101–3(b)(3)

Like the interim final rule, paragraph (b)(3) of the final rule provides that the blackout notice must be in writing and may be furnished in any manner permitted under 29 CFR 2520.104b–1, including through electronic media. One commenter indicated that the ''reasonably accessible'' standard of the SOA is intended to be broader than the standards under § 2520.104b–1 and the regulation, therefore should be modified accordingly. The Department disagrees with the commenter's interpretation of the statute. It is the view of the Department that the standards set forth in § 2520.104b–1(c), relating to the use of electronic media, are intended to ensure reasonable access to electronic communications by participants and beneficiaries consistent with the statute. Accordingly, the provision of the interim final regulation is being retained without modification.

In the preamble to the interim final rule, the Department indicated that a blackout notice will be considered furnished as of the date of mailing, if mailed by first class mail, or as of the date of electronic transmission, if transmitted electronically. Two commenters indicated that the circumstances under which a notice is considered to be furnished should be

expanded to include delivery by overnight mail, third class mail, private delivery services, and interoffice mail. It is the view of the Department that interoffice mail is essentially hand delivery and, therefore, a document would not be considered furnished until received by the participant. On the other hand, the Department agrees that with the commenters that there are other methods of delivery that should be accorded the same deference as electronic transmission and first class mail. In this regard, it is the view of the Department that a blackout notice will be considered furnished on the date of mailing if it is accomplished by first class mail, certified mail or Express Mail; or on the date of delivery to a ''designated private delivery service'' within the meaning of 26 U.S.C. 7502(f). In the case of notices furnished electronically, notices will be considered furnished on the date of transmission.

One commenter requested clarification of whether furnishing notice to the last known address of a participant or beneficiary is sufficient. Furnishing a notice to the last known address of a participant or beneficiary would be sufficient where the plan utilizes a method of delivery described in § 2520.104b–1 and the fiduciaries of the plan have taken reasonable steps to keep plan records up-to-date and to locate lost or missing participants.

5. Changes in Length of Blackout Period § 2520.101(b)(4)

Paragraph (b)(4) describes the notice requirements applicable to changes in the length of the blackout period. The final rule, like the interim final rule, provides that the administrator is required to provide all affected participants and beneficiaries with an updated notice explaining the reasons for the change in the date(s) and identifying all material changes in the information contained in the prior notice. The updated notice must be provided as soon as reasonably possible, unless such notice in advance of termination of the blackout period is impracticable. In this regard, the Department reiterates that to the extent that an administrator has the ability to furnish notice to some participants and beneficiaries earlier than other participants and beneficiaries, which may be the case where electronic disclosure is available, the administrator has an obligation to provide such notice, even though providing advance notice to other participants and beneficiaries (*e.g.*, by mail) may be impracticable.

6. Notice to Issuer of Employer Securities § 2520.101–3(c)

Paragraph (c) of § 2520.101–3 of the final rule, like the interim final rule, describes the plan administrator's obligation to provide notice of a blackout period to the issuer of employer securities held by the plan and subject to the blackout period. Paragraph (c)(1) generally provides that the content and timing requirements applicable to the furnishing of notices to participants and beneficiaries also apply to the furnishing of notices to the issuer of employer securities. As with the interim final rule, it is the view of the Department that a plan administrator may satisfy its obligation to notify the issuer by providing the same notice furnished to participants and beneficiaries. Paragraph (c)(2) provides that the notice of the blackout period shall be furnished to the agent for service of legal process for the issuer, unless the issuer has provided the plan administrator the name of another person for service of such notice. Paragraph (c)(2) is intended to ensure that there is no ambiguity as to whom the administrator must serve notice of the blackout period. Pursuant to section 306(a)(6) of the SOA, issuers are required to notify directors, executive officers, and the Securities and Exchange Commission of the blackout period.

Three commenters suggested that notice to the issuer should not be required when the plan administrator and issuer are the same person. The Department does not believe that merely because an issuer and the plan administrator may, as a technical matter, be the same legal entity, that the parties will necessarily be privy to the same information. Nonetheless, there is nothing in the regulation that precludes an issuer of employer securities from designating the plan administrator as the party to receive notices of blackout periods. The Department has amended the regulation, at § 2520.101–3(c), to add a new subparagraph (3) making clear that where an issuer designates the administrator as the person to be furnished notice of a blackout period, the issuer shall be deemed to have been furnished notice on the same date as notice is furnished to affected participants and beneficiaries, thereby relieving the administrator of the obligation to notify itself of a blackout period.

7. Definitions § 2520.101–3(d)

a. ''Blackout Period''

Paragraph (d)(1) of § 2520.101–3 defines the term ''blackout period.'' The interim final rule adopted the definition set forth in ERISA section 101(i)(7). The Department received a number of comments on the interim final regulation requesting clarification of specific exclusions from the ''blackout period'' definition, as well as clarification that certain suspensions, limitations or restrictions imposed on an individual participant's account do not constitute a blackout period as contemplated by the statute or regulation.

''Regularly Scheduled'' Exclusion

One commenter requested a clarification that the provisions of paragraph (d)(1)(ii)(B), relating to ''a regularly scheduled suspension, limitation or restriction,'' not only applies to those that are plan changes, but also to preexisting plan features. Another commenter requested clarification that ''a regularly scheduled suspension, limitation, or restriction'' may, for purposes of the exclusion, be contained in and disclosed via enrollment forms, investment policies and other documents pursuant to which the plan is established or operated.

First, the Department does not believe that Congress, in enacting ERISA section 101(i)(7), intended to include preexisting regularly scheduled suspensions, limitations, or restrictions in the definition of the blackout period to the extent such suspensions, limitations, or restrictions are disclosed to participants and beneficiaries. In this regard, the Department notes that section 101(i)(7)(A) of ERISA and paragraph (d)(1)(i) of the regulation, in defining ''blackout period,'' references ''any period for which any ability of participants or beneficiaries under the plan, which is otherwise available under the terms of such plan, to direct or diversify assets * * *.'' (Emphasis supplied). The Department reads the clause ''which is otherwise available under the terms of such plan'' as referring to preexisting regularly scheduled suspensions, limitations or restrictions. The Department also notes that the ''blackout period'' definition contained in SOA section 306(a)(4), to be administered by the Securities and Exchange Commission, generally provides that a blackout period does not include ''a regularly scheduled period,'' if such period is incorporated into the plan and timely disclosed to employees. Nonetheless, in an effort to clarify this issue and more closely align the exclusion in ERISA section 101(i)(7)(B)(ii) with SOA section 306(a),

the Department has amended paragraph (d)(1)(ii)(B) of the regulation.[1]

As amended, paragraph (d)(1)(ii)(B) excludes from the definition of blackout period a suspension, limitation or restriction ''which is a regularly scheduled suspension, limitation, or restriction under the plan (or change thereto), provided that such suspension, limitation or restriction (or change) has been disclosed to affected plan participants and beneficiaries through the summary plan description, a summary of material modifications, materials describing specific investment alternatives under the plan and limits thereon or any changes thereto, participation or enrollment forms, or any other documents and instruments pursuant to which the plan is established or operated that have been furnished to such participants and beneficiaries.'' This amendment also serves to clarify that ''regularly scheduled suspensions, limitations and restrictions'' may be set forth in and disclosed to participants and beneficiaries in a variety of documents.

The amendment to paragraph (d)(1)(ii)(B), by reference to ''materials describing specific investment alternatives under the plan and limits thereon,'' also is intended to make clear that restrictions on investments or delays in payment or transfers applicable to particular investments are encompassed within the exclusion to the extent disclosed to affected participants and beneficiaries. Similarly, limits on the ability of participants and beneficiaries to give investment instruction (such as limits on the ability of participants to trade daily) would be covered by the exclusion as a ''regularly scheduled suspension, limitation or restriction'' to the extent disclosed to affected participants and beneficiaries.

A number of commenters requested clarification that quarterly freezes on trading involving employer stock, timed to coincide with earnings reports and intended to prevent insider trading, whether fixed dates or determined on a quarter-by-quarter basis, do not constitute blackout periods within the meaning of the regulation when plan materials disclose the dates or explain how the dates will be determined. It is the view of the Department that such restrictions on trading employer securities would be ''regularly scheduled'' to the extent the event (*i.e.*, release of the company's quarterly earnings report) and the restriction (freeze on trading employer securities) and the period of the restriction are described in plan materials and disclosed to the plan's affected participants and beneficiaries.

QDRO Exclusion

A number of commenters also expressed concern that the language of paragraph (d)(1)(ii)(C), relating to suspensions, limitations, or restrictions as a result of a qualified domestic relations order (QDRO), did not take into account the obligations of a plan administrator to impose certain restrictions on the account of a participant during the pendency of a determination as to whether a domestic relations order is qualified. Given the specific obligations imposed on plan administrators pursuant to ERISA section 206(d)(3)(H), the Department does not believe that Congress, in drafting section ERISA 101(i)(7)(B)(iii), intended to limit the subject exclusion only to those restrictions arising after a determination that a domestic relations order is qualified. Accordingly, the Department has amended paragraph (d)(1)(ii)(C) to clarify the application of the exclusion to restrictions imposed during the pendency of a QDRO determination. As amended, paragraph (d)(1)(ii)(C) excludes a suspension, limitation or restriction ''which occurs by reason of a qualified domestic relations order or by reason of a pending determination (by the plan administrator, by a court of competent jurisdiction or otherwise) whether a domestic relations order filed (or reasonably anticipated to be filed) with the plan is a qualified order within the meaning of section 206(d)(3)(B)(i) of ERISA.''[2]

Individual Participant Actions

Commenters generally requested clarification that the term ''blackout period'' is not intended to include account restrictions triggered by individual participant actions. Examples of such actions include: Receipt of a tax levy, a dispute over a deceased participant's account among putative beneficiaries, failure of a participant to obtain a PIN number, or allegations that the participant committed a fiduciary breach or crime involving the plan. It is the view of the Department that Congress did not intend to encompass within the meaning of ''blackout period'' restrictions on investment direction, plan loans and plan distributions imposed solely in response to an action involving an individual participant and affecting only the account of that participant, such as those actions identified in the preceding sentence. Rather, the blackout notice requirements are intended to ensure that plan participants and beneficiaries are afforded advance notice of plan-imposed restrictions on their rights in order that they may take appropriate steps in anticipation of the restriction. In the case of actions involving individual participants, the Department agrees with commenters that the affected participant or beneficiary typically will already have notice of any restriction and reasons for such restriction. In response to these comments, the Department has amended the definition of blackout period at paragraph (d)(2) of the regulation to clarify that suspensions, limitations and restrictions precipitated by a participant's action or the action of a third-party with respect to an individual participant's account are excluded from the definition of ''blackout period.'' Specifically, new paragraph (d)(2)(D) excludes from definition of blackout periods, a suspension, limitation and restriction that ''occurs by reason of an act or a failure to act on the part of an individual participant or by reason of an action or claim by a party unrelated to the plan involving the account of an individual participant.[3]

Permanent Restrictions

Commenters, noting that the definition of ''blackout period'' refers to rights that are ''temporarily suspended, limited or restricted,'' requested clarification that permanent elimination of certain rights would not constitute a ''blackout period.'' Examples cited by the commenters included: Permanent restriction on new contributions to an investment option, replacement of one investment option with another of a similar type, and termination of the plan. The Department agrees that the blackout notice requirements were not

[1] Section 101(i)(5) of ERISA, as added by SOA section 306(b), provides that the Secretary may establish by regulation additional exceptions to the requirements of subsection (i) of section 101 (the blackout notice requirements) which the Secretary determines are in the interest of participants and beneficiaries. The Department finds the amendment to paragraph (d)(1)(ii)(B) of the regulation to be in the interest of participants and beneficiaries.

[2] Pursuant to the Department's authority under section 101(i)(5) of ERISA, the Department finds the amendment to paragraph (d)(1)(ii)(C) to be in the interest of plan participants and beneficiaries.

[3] Section 101(i)(5) of ERISA, as added by SOA section 306(b), provides that the Secretary may establish by regulation additional exceptions to the requirements of subsection (i) of section 101 (the blackout notice requirements) which the Secretary determines are in the interest of participants and beneficiaries. The Department finds this amendment to paragraph (d)(2) of the regulation to be in the interest of participants and beneficiaries.

intended to apply to rights that are eliminated, as opposed to temporarily suspended, limited or restricted. Accordingly, a permanent restriction on new contributions to an investment option, replacement of one investment option with another, a plan termination and similar types of permanent restrictions would not in and of themselves be events that give rise to a blackout notice obligation under the regulation. However, if, in connection with implementing a permanent restriction, some rights would be temporarily suspended, limited or restricted, the blackout notice requirements would apply to such temporary restriction. For example, in replacing investment option A with investment option B, the plan permanently restricts new contributions to option A and during the transfer of funds from option A to option B temporarily suspends participant direction of the funds transferred to option B for 5 days during which transfers and accounts will be reconciled. In this situation, the restriction on new contributions to option A would not constitute a blackout period, but the 5 day temporary restriction on the direction of funds in option B would constitute a blackout period with respect to which notice must be provided under the regulation. On the other hand, if there was no restriction on the direction of funds in option B or if the restriction was for 3 or fewer consecutive business days, there would be no blackout period with regard to such funds under the regulation.

One commenter requested a clarification that a blackout period does not occur solely because of the bankruptcy of an employer and the appointment of a bankruptcy trustee or as a result of abandonment of a plan by the plan sponsor. Such actions would, in the view of the Department, result in a blackout period only if the rights of participants and beneficiaries to direct investments, obtain a loan or obtain a distribution are temporarily suspended, limited or restricted within the meaning of the regulation. In the event there is a blackout period in connection with such actions, notice would have to be provided by the plan administrator or the party assuming the responsibilities of the plan administrator.

One commenter requested clarification that the definition of ''blackout period'' does not extend to suspensions, limitations or restrictions of services (such as investment education, investment advice, retirement counseling, financial planning) that may facilitate the exercise of a participant's and beneficiary's right to diversify their assets, obtain a loan or obtain a distribution. It is the view of the Department that to the extent such services are not required in order for a participant or beneficiary to exercise his or her right to direct investments, obtain a loan or obtain a distribution, the suspension, limitation or restriction of such services would not give rise to a blackout period within the meaning of the regulation.

b. ''One-Participant Retirement Plan''

As with the interim final rule, the final rule adopts the statutory definition of ''one-participant retirement plan'' set forth in section 101(i)(8)(B) of ERISA, as amended by section 306(b)(1) of the SOA. One commenter suggested the definition of ''one-participant retirement plan'' be amended to apply the definition in 29 CFR § 2510.3–3(c)(1) and (2) for purposes of the blackout notice requirements. The Department has not adopted this suggestion and retained the statutory definition ''one-participant retirement plan'' without change.

c. ''Issuer''

Like the interim final rule, paragraph (d)(4) of the final rule defines the term ''issuer'' for purposes of the blackout notice provisions. Consistent with the provisions of section 2(a)(7) of the SOA, issuer means an issuer as defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c),[4] the securities of which are registered under section 12 of the Securities Exchange Act of 1934, or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934, or files or has filed a registration statement that has not yet become effective under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), and that it has not withdrawn.

d. Miscellaneous

In response to requests from two commenters, the Department provides the following clarifications. First, references to plan administrator and administrator in the regulation mean the ''administrator'' as defined in section 3(16)(A) of ERISA. Second, the term ''affected participant'' as used in the regulation means participants and beneficiaries whose rights under the plan are affected by the suspension, limitation, or restriction of their right to direct or diversity assets, obtain a loan or obtain a distribution. Employees who are eligible but who have not elected to participate in the plan would not be ''affected participants'' within the meaning of the regulation.

8. Model Notice § 2520.101–3(e)

Paragraph (e) of § 2520.101–3 provides a model notice to facilitate compliance with the blackout notice requirements by plan administrators. Use of the model is not mandatory. However, like the interim final rule, the final rule provides that use of the advisory statement set forth at paragraph 4 of the model notice will be deemed to satisfy the notice content requirements of paragraph (b)(1)(iv) of the rule pertaining to advising participants and beneficiaries about the importance of reviewing their plan investments in anticipation of their inability to direct or diversify their investments during the blackout period. The final rule, like the interim final rule, also provides that use of the general statement set forth in paragraph 5 of the model notice will be deemed to satisfy the requirement of paragraph (b)(1)(v)(A) that the notice contain a general statement that Federal law requires furnishing of blackout notices in advance of the blackout period.

This model is intended to deal solely with the content requirements prescribed in paragraph (b)(1) and not other matters with respect to which disclosure may be required, such as changes in investment options.

As discussed earlier, the model notice has been revised to accommodate changes in the final rule. Paragraph 3 of the model (relating to length of the blackout period) has been changed to reflect alternative approaches to describing the length of the blackout period and paragraph 4 (encouraging participants and beneficiaries to review their investments in anticipation of the blackout period) has been modified to make clear that the last two sentences of the paragraph (relating to investments in individual securities) apply only to plans that offer investments in individual securities. Paragraph 6 of the model also was modified to make clear that individual persons are not required to be named as contacts for information about blackout periods.

[4] Section 3 of the Securities Exchange Act of 1934 defines the term ''issuer'' to mean any person who issues or proposes to issue any security; except that with respect to certificates of deposit for securities, voting-trust certificates, or collateral-trust certificates, or with respect to certificates of interest or shares in an unincorporated investment trust not having a board of directors or of the fixed, restricted management, or unit type, the term ''issuer'' means the person or persons performing the acts and assuming the duties of depositor or manager pursuant to the provisions of the trust or other agreement or instrument under which such securities are issued; and except that with respect to equipment-trust certificates or like securities, the term ''issuer'' means the person by whom the equipment or property is, or is to be, used.

One commenter suggested that paragraph 4 of the model not be required when notice is furnished as soon as reasonably possible under the circumstances, but after the date on which affected participants and beneficiaries can take action in anticipation of the blackout period. The Department agrees that including paragraph 4 of the model in a notice furnished after the date on which participants and beneficiaries can effectuate changes in anticipation of the blackout period will be of no value to participants and beneficiaries and, accordingly, may be deleted.

One commenter suggested that the model advise participants of the tax consequences relating to net unrealized appreciation of employer securities upon distribution from a plan. The Department believes that, while such information may be useful to participant, the information goes beyond the scope of the intended blackout notice. The Department notes, however, that there is nothing in the regulation which precludes the furnishing information with the blackout period notice that may be helpful to plan participants and beneficiaries.

9. Effective Date § 2520.101–3(f)

Paragraph (f) of § 2520.101–3 sets forth the effective date of the final rule. Like the interim final rule, paragraph (f) provides that the rule is effective on January 26, 2003, the effective date of the SOA section 306 amendments to ERISA. Paragraph (f) provides that the notice requirements shall apply to blackout periods commencing on or after January 26, 2003, and that, for blackout periods beginning between January 26, 2003 and February 25, 2003, plan administrators shall furnish notice as soon as reasonably possible. This provision is intended to ensure that a statutorily required notice be provided with respect to blackout periods which commence before February 26, 2003. In no event, however, is a blackout notice required to be furnished under the regulation prior to the January 26 effective date. Pursuant to section 553(c) of the Administrative Procedure Act, the Department finds good cause for this rule to be effective less than 30 days after publication. The Department believes that having the rule effective on the effective date of the underlying statutory provisions will avoid confusion for plan administrators. Moreover, the limited extent of the differences between the instant rule and the interim rules will minimize any difficulties in complying with the rule by the effective date.

C. Regulatory Impact Analysis

Summary

The costs associated with this final rule arise primarily from the statutory requirement to prepare and distribute advance notices of the imposition of blackout periods. The aggregate costs for plans required to provide this notice are estimated to be $13.9 million per year. The benefits afforded participants and beneficiaries and plan administrators by the statute and final rule cannot be quantified, but are expected to be substantial. These requirements will ensure that notices are always provided, are timely, and have appropriate content. Economic benefits will accrue to participants or beneficiaries as a result of their enhanced ability to exercise control over their retirement plan assets with adequate information to inform their decisions. The assurance of receiving advance notice of events that may be critical to participant decisionmaking will increase confidence in the security of retirement assets and promote plan participation. The statute and this guidance will also assist plan administrators in their efforts to fulfill their obligations to participants and beneficiaries.

Benefits and Costs

The SOA amendments to ERISA and this implementing guidance will have several important benefits. First, while commenters on the interim final rule confirm that many plan administrators currently provide disclosures similar to those required by the statute and interim final rule, these new requirements will ensure that appropriate information is provided in a consistent and timely manner.

This advance knowledge will have economic value and increase confidence in the security of retirement savings. Timely notice and an understanding of the reasons for and expected duration of a blackout period will benefit participants and beneficiaries economically by offering them ample opportunity to assess their current investment decisions, and to adjust their exposure to loss if they wish to do so, to the extent possible within the existing options available under the plan. Advance notice of blackout periods cannot eliminate fluctuations of market value during a period when existing investment instructions cannot be modified. However, notice will allow affected participants and beneficiaries to maximize their exercise of control as they deem appropriate in their individual circumstances.

Assurance of the opportunity to exercise control with adequate knowledge, in advance of events that will affect their ability to exercise control, will increase participant and beneficiary confidence that the plan is being operated appropriately. Participants frequently express concern when significant changes are made to plan options, or when rights previously available are temporarily limited. Assuring that they will have knowledge of the timing and reasons for such changes should serve to promote confidence in the security of retirement savings and support continued growth in participation in the retirement plans offered by plan sponsors.

Second, guidance on the statutory notice requirement will benefit plan sponsors and administrators by clarifying the manner in which they may discharge their obligation to ensure that participants and beneficiaries have access to information necessary to make informed and meaningful investment decisions. Blackout periods occur for a variety of reasons. Their occurrence and timing are often, but not always, within the control of the plan administrator. The most common reasons for imposition of a blackout period include changes in investment alternatives or recordkeepers, and corporate mergers, acquisitions, and spin-offs that impact the pension coverage of groups of participants. Plan administrators will wish to ensure that proper accounting and record transfer is accomplished as timely and accurately as possible, while at the same time advising participants about important matters affecting their rights under the plan.

The value of these benefits cannot be specifically quantified. However, the conclusion that advance notice of blackout periods produces economic benefits is consistent with mainstream economic theory and corroborated by evidence. For example, theory posits that financial market prices respond quickly to new information. Delays in executing trades have been shown to be costly. Advance notice of a blackout in trading enables affected participants to adjust their positions to manage their exposure to such costs. The benefits are expected to outweigh the costs of the statute and the final rule.

Administrators of about 85,150 affected plans are estimated to incur costs of approximately $13.9 million each year to prepare and distribute blackout notices to 12 million covered participants. This total consists of about $8 million per year for 295,000 small plans (an average of about $110 per plan), and $5.8 million per year for 45,000 large plans (an average of about $510 per plan). These costs are primarily attributable to the effect of the

statutory provisions, and would in fact be estimated to be greater in the absence of a model notice due to higher notice drafting time. Because plans commonly provide advance notice of blackout periods voluntarily, much of this cost is inherent in normal business practice, and the incremental cost attributable to the advance notice requirement will be less than total estimated here. Because the costs of the statute arise from notice provisions, the data and methodology used in developing these estimates are fully described in the Paperwork Reduction Act section of this statement of regulatory impact.

Although the Department requested input from the public concerning the assumptions used in developing these estimates, the likely frequency of blackout periods, the sources of variability in the costs and benefits of providing notices, and any potential differential impacts on small plans, it received a limited number of comments addressing economic impact. As noted earlier in this preamble, several commenters indicated that the interim final rule's requirement for the disclosure of specific beginning and ending dates in the blackout notice, and a corresponding frequency of the requirement for subsequent notices arising from the inability to predict specific dates, would add to the burden of the blackout notice requirement. The Department has made certain modifications in the final rule to address these concerns. A comment was also received with respect to the Department's assumptions with respect to the use of electronic methods of communication. This comment is addressed in the Paperwork Reduction Act statement below.

Executive Order 12866

Under Executive Order 12866 (58 FR 51735), the Department must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined that this final rule is significant within the meaning of section 3(f)(4) of the Executive Order. OMB has, therefore, reviewed the final rule pursuant to the Executive Order.

Paperwork Reduction Act

At the time of publication of the interim final rule, the Department of Labor submitted the information collection request (ICR) included in the interim final rule to OMB for review and clearance in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995 (PRA 95). OMB subsequently approved the information collection using emergency clearance procedures on December 5, 2002. This emergency clearance will expire on April 30, 2003. As a consequence, the information collection included in this final rule is being submitted at this time for continuing approval. The burden estimates are unchanged, and terms of the final rule that constitute collections of information are not substantively or materially changed. A copy of the ICR with applicable supporting statement may be obtained by calling the Department of Labor, Ms. Marlene Howze, at (202) 693–4158, or by e-mail to *Howze-Marlene@dol.gov*.

Comments and questions about the ICR should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, ATTN: Desk Officer for the Pension and Welfare Benefits Administration, Room 10235, 725 17th Street, NW., Washington, DC 20503 ((202) 395–7316). Comments should be submitted to OMB by February 24, 2003 to ensure their consideration.

The Department and OMB are particularly interested in comments that:

- 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.

Information Collection Provisions

The information collection provisions of this final rule are found in paragraphs (a), (b)(2)(ii)(A) and (B), (b)(2)(iv), (b)(4), and (c)(1). A model notice is provided in paragraph (e) to facilitate compliance and moderate the burden associated with supplying notices to participants and beneficiaries as described in the final rule. Use of the model notice is not mandatory, and the addition of other relevant information to the advance notice should not be viewed as restricted by the model. Modifications described earlier in this preamble to paragraphs (b)(1)(iii)(A) and (B) allowing the use under specific circumstances of a limited range of beginning and ending dates rather than specific dates should serve to allow for greater flexibility and limit the number of follow-up notices required pursuant to paragraph (b)(4). New paragraph (c)(3) clarifies that where an issuer designates the plan administrator as the person to receive notice under paragraphs (c)(1), the plan administrator need not supply this notice separately to itself. This modification may eliminate the need for duplicate notification under some circumstances. Neither of these changes is considered to constitute a substantive or material change to the existing approved information collection.

Comments

As noted, the Department received comments concerning the difficulty of including specific beginning and ending dates in the notice pursuant to paragraphs (b)(1)(iii), and the applicability of the notice requirement of paragraph (c) when an issuer designates the plan administrator as the party to receive notices of blackout periods affecting securities of the issuer. The Department has addressed these and other issues raised by commenters with modifications previously described in this preamble. In addition, one commenter expressed the view that the Department's estimates were understated to the extent that they incorporated the use of electronic media for distribution of the notices. The commenter further stated that the use of electronic technology for communicating with participants and

beneficiaries is generally not viable due to the absence of computer capability in certain industries. While the Department did not describe its methodology for incorporating electronic disclosure assumptions in detail in the interim final rule, the methodology does take a variety of factors into account, including the distribution of plan sponsors and participants across industries, data related to access to computers in different industries, survey data on the use of electronic communication methods by plan sponsors and administrators, and comments received in response to the Department's Notice of Proposed Rulemaking on Use of Electronic Communication and Recordkeeping Technologies by Employee Pension and Welfare Benefit Plans (64 FR 4506, January 28, 1999; finalized April 9, 2002, 67 FR 17264).

Specifically, in order to develop estimates of distribution expenses saved through the use of electronic communication technologies, the Department utilized a Census Bureau household survey published in 2001 on computer use [5] and a separate 1999 Census Bureau household survey [6] on pension and health benefit plan participation. Analysis of this information indicates that approximately 21 percent of participants have appropriate access to electronic media at their workplaces, and another 38 percent have such access at home. The pension and health coverage rates were then applied to the computer use rates industry-by-industry to account for the likelihood that computer use is greater among plan participants and especially among large plan participants, because such participants are concentrated in certain industries (*e.g.*, the financial services industry).

The Department then looked at each disclosure required under Title I of ERISA to evaluate the extent to which plan administrators might consider electronic distribution appropriate. For purposes of the required notices of blackout periods, it was assumed that in most cases where plan administrators and participants had consistent access to computers, these notices would be distributed electronically. This is because it is believed that plan administrators will consider the information time sensitive, because electronic distribution is cost effective, and because the investment companies that provide administrative services for many individual account plans commonly communicate with customers in an electronic format.

While the description of the use of electronic technologies in the preamble to the interim final rule may have been read to suggest that most or all blackout notices were expected to be delivered electronically, the delivery of the majority of notices is in fact still estimated to occur by first class mail. About 38 percent of such notices are expected to be delivered electronically. While the Department agrees with the commenter that many plans will derive no benefit from electronic distribution, it has carefully considered its approach to estimating distribution savings for plans situated to make use of electronic technologies, and continues to believe that the approach supports reasonable estimates.

Accordingly, it has not modified its previous assumptions concerning the likely methods of delivery for notices of blackout periods.

Burden Estimates

In order to estimate the potential costs of the notice provisions of section 101(i) of ERISA and this final rule, the Department tabulated the number of participant-directed individual account plans and the number of participants, inactive participants and beneficiaries who have not taken distributions, in those plans using the plans' Form 5500 filings for 1998, the most recent year currently available. The Department then projected these counts forward, producing estimates of 295,000 small and 45,000 large participant-directed individual account plans in 2002 (totaling 341,000). Participant counts were also projected, resulting in estimates of 7.4 million small plan participants and 40.4 large plan participants (totaling 47.8 million) in 2002 that would potentially be affected by blackout notices. A more detailed explanation of the methods and data used in these projections, as well as assumptions underlying the proportion of these plans and participants expected to be affected each year may be found in the preamble to the interim final rules.

Based on available data, the Department assumes that 25% percent of potentially affected plans will impose a blackout period in any given year. The resulting numbers of plans and participants assumed to be affected by the notice provisions annually are 85,150 and about 12 million, respectively.

The availability of a model notice as provided in paragraph (e) will lessen the time otherwise required to draft a required notice. In developing burden estimates, the Department has allowed one-half hour for drafting of the elements of the form by the plan administrator, and one hour for legal review of the drafted notice, the latter expense to be incurred as a payment of fees for outside services. This accounts for the burden of preparing the notice, which is estimated at 42,600 hours, and $6.4 million. No additional preparation time is accounted for to draft the notice required to be provided to an issuer of employer securities under paragraph (c), because this final rule requires the content and timing of that notice to be the same as the notice prepared for the purpose of paragraph (b)(1). The burden of this notice would be driven by the number of plans rather than participants, and the notice would be required in far more limited circumstances than the notice to participants under paragraph (b)(1), as it pertains only to the issuer's securities affected by the blackout period in the plan. In addition, based on the addition of paragraph (c)(3), when the issuer designates the plan administrator as the party to receive of blackout periods involving securities of the issuer, the plan administrator is not required to provide this notice separately to itself. This modification should serve to reduce the number of these notices because the issuer and plan administrator are in some instances the same entity; however, the magnitude of the reduction cannot be estimated. Because only a small segment of participant directed individual account plans holds employer securities that would be subject to the requirements of paragraph (c), the cost of delivering such notices is estimated to be negligible.

The estimated burden for distribution of blackout notices takes several factors into account, including an assumed number of participants affected annually, the number of the notices that will be distributed electronically, and on paper, and the differential costs of electronic and paper distribution methods. The estimates of the rate of use of electronic distribution methods are consistent with those used in determining the savings associated with the Department's Final Rules Relating to Use of Electronic Communication and Recordkeeping Technologies by Employee Pension and Welfare Benefit Plans (67 FR 17264, April 9, 2002). Those participants not calculated to receive notice electronically are

[5] "Home Computers and Internet Use in the United States: August 2000," U.S. Census Bureau Current Population Reports (September 2001).

[6] Contingent Work Supplement to the February, 1999 Current Population Survey, U.S. Census Bureau.

assumed to receive the notice on paper. Paper distribution is estimated to require one minute per notice for copying and mailing, plus $0.40 for paper and postage. No time or direct cost is attributed to electronic distribution methods other than the time required to prepare the notice, because it is assumed that notices are drafted in electronic form, plan administrators use existing infrastructure to communicate electronically, and the cost of electronic transmission is negligible. Paper notice distribution is estimated to require 123,500 hours, and cost about $3 million annually.

The Department considers that this distribution burden estimate is conservatively high due to the fact that many plans already provide advance notices in the event of the imposition of a blackout period, that most blackout periods arise from changes in investment providers or recordkeepers, and that this advance notice either is or will be included with other informational materials that would ordinarily be supplied to participants or beneficiaries to implement that change. Commenters were generally in agreement with these assumptions.

No additional burden is included for the requirements for written documentation that is to be dated and signed under paragraphs (b)(2)(ii)(A) and (B) and (b)(2)(iv). It is assumed that written documentation is normally maintained in the circumstances described, and that the burden of adding a signature or providing a limited number of copies upon request would be negligible.

Further, no additional burden is estimated for subsequent notices required due to changes described in paragraph (b)(4). The Department has no basis for an estimate of the frequency of changes in the length of blackout periods. Further, the Department believes that, although a cost is incurred to do so, plan administrators typically inform participants of changes in the duration of a blackout period as part of their reasonable and customary business practices. It is acknowledged that the content and timing might be modified based on the provisions of the SOA and this final rule, however. As noted earlier, the modification of the interim final rule provision describing the nature of the information to be included on blackout period beginning and ending dates should serve to minimize the number of subsequent notices and their attendant costs by clarifying for plan administrators the extent to which their usual practices conform to the provisions of the final rule.

The current estimates of annual respondents, responses, and hour and cost burdens are shown below.

Type of Review: Extension of a currently approved collection.

Agency: Department of Labor, Pension and Welfare Benefits Administration.

Title: Notice of Blackout Period under ERISA.

OMB Number: 1210–0122.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 85,150.

Frequency of Response: On occasion.

Responses: 11,956,000.

Estimated Total Burden Hours: 166,129.

Total Annual Cost (Operating and Maintenance): $ 9,351,400.

OMB will consider comments submitted in response to this request in its review of the request for an extension of the emergency approval of the ICR; these comments will also become a matter of public record.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. For purposes of its analyses under the RFA, PWBA continues to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reporting for pension plans that cover fewer than 100 participants. Because this guidance is issued as a final rule pursuant to the authority and deadlines prescribed in section 306(b)(2) of the SOA, RFA does not apply, and regulatory flexibility analysis is not required.

The terms of the statute pertaining to the required notices to plan participants and beneficiaries in the event of a blackout do not vary relative to plan size. This final rule addresses the statutory provisions, which are self-executing and do not afford the Department with substantial discretion to exercise regulatory flexibility with respect to small plans. While a cost is expected to be associated primarily with the statutory provisions, the Department believes that the final rule imposes no additional cost on small plans. The Department nevertheless requested comments concerning any special issues facing small plans with respect to blackout notices, and any alternatives consistent with the objectives of the statute that may serve to facilitate compliance. No comments were received in response.

As to the potential impact of the final rule on small plans, the Department notes that available data suggest that about 341,000 plans, or 47 % of all plans are potentially impacted by the enactment of a blackout notice requirement, in that they are individual account plans that permit any form of individual investment direction.

The statutory blackout notice requirement will potentially affect a significant number of small plans. About 87% of the potentially affected plans are small. However, although most affected plans are small, the participants in those plans represent only about 16% of the 47.8 million potentially affected participants. Based on the assumption that plans will impose a blackout period once every four years on average, about 73,800 small plans and 11,400 large plans will prepare and distribute notices annually. The small affected plans represent about 10% of all pension plans, while the large affected plans represent about 2% of all plans. Affected participants (1.9 million in small plans, and 10.1 million in large plans) represent approximately 2% and 9% of all plan participants, respectively.

The substance of the required notice is likely to be prepared once per plan for each applicable blackout period and distributed to the multiple affected participants. The fixed cost of preparing the notice is estimated at approximately $100 for both large and small plans. The total cost to affected small plans for both preparation and distribution is expected to be an average of about $110 per year. The comparable annual average cost to large plans of about $510 is substantially greater due to the greater numbers of participants in these plans, and the costs attendant to distribution of the notices.

Congressional Review Act

The rules being issued here are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review. The rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State, or local

government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, this final rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, and does not impose an annual burden exceeding $100 million on the private sector.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of 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. This final rule does not have federalism implications because it has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in this final rule do not alter the fundamental reporting and disclosure requirements of the statute with respect to employee benefit plans, and as such have no implications for the States or the relationship or distribution of power between the national government and the States.

List of Subjects in 29 CFR Part 2520

Employee benefit plans, Employee Retirement Income Security Act, Pensions, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, amend part 2520 of Title 29 of the Code of Federal Regulations as follows:

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

1.The authority citation for part 2520 continues to read as follows:

Authority: 29 U.S.C. 1021–1025, 1027, 1029–31, 1059, 1134 and 1135; Secretary of Labor's Order No. 1–87.

Sections 2520.102–3, 2520.104b–1 and 2520.104b–3 also issued under 29 U.S.C. 1003, 1171–73, 1185 and 1191–94; and under sec. 101(g)(4), Pub. L. 104–191, 110 Stat. 1936.

Sections 2520.104b–1 and 2520.107 also issued under sec. 1510, Pub. L. 105–34, 111 Stat. 788.

Section 2520.101–3 also issued under sec. 306(b)(2), Pub. L. 107–204, 116 Stat. 745.

2. Revise § 2520.101–3 to read as follows:

§ 2520.101–3 Notice of blackout periods under individual account plans.

(a) *In general.* In accordance with section 101(i) of the Act, the administrator of an individual account plan, within the meaning of paragraph (d)(2) of this section, shall provide notice of any blackout period, within the meaning of paragraph (d)(1) of this section, to all participants and beneficiaries whose rights under the plan will be temporarily suspended, limited, or restricted by the blackout period (the ''affected participants and beneficiaries'') and to issuers of employer securities subject to such blackout period in accordance with this section.

(b) *Notice to participants and beneficiaries*—(1) *Content.* The notice required by paragraph (a) of this section shall be written in a manner calculated to be understood by the average plan participant and shall include—

(i) The reasons for the blackout period;

(ii) A description of the rights otherwise available to participants and beneficiaries under the plan that will be temporarily suspended, limited or restricted by the blackout period (*e.g.,* right to direct or diversify assets in individual accounts, right to obtain loans from the plan, right to obtain distributions from the plan), including identification of any investments subject to the blackout period;

(iii) The length of the blackout period by reference to:

(A) The expected beginning date and ending date of the blackout period; or

(B) The calendar week during which the blackout period is expected to begin and end, provided that during such weeks information as to whether the blackout period has begun or ended is readily available, without charge, to affected participants and beneficiaries, such as via a toll-free number or access to a specific web site, and the notice describes how to access the information;

(iv) In the case of investments affected, a statement that the participant or beneficiary should evaluate the appropriateness of their current investment decisions in light of their inability to direct or diversify assets in their accounts during the blackout period (a notice that includes the advisory statement contained in paragraph 4. of the model notice in paragraph (e)(2) of this section will satisfy this requirement);

(v) In any case in which the notice required by paragraph (a) of this section is not furnished at least 30 days in advance of the last date on which affected participants and beneficiaries could exercise affected rights immediately before the commencement of the blackout period, except for a notice furnished pursuant to paragraph (b)(2)(ii)(C) of this section:

(A) A statement that Federal law generally requires that notice be furnished to affected participants and beneficiaries at least 30 days in advance of the last date on which participants and beneficiaries could exercise the affected rights immediately before the commencement of a blackout period (a notice that includes the statement contained in paragraph 5. of the model notice in paragraph (e)(2) of this section will satisfy this requirement), and

(B) An explanation of the reasons why at least 30 days advance notice could not be furnished; and

(vi) The name, address and telephone number of the plan administrator or other contact responsible for answering questions about the blackout period.

(2) *Timing.* (i) The notice described in paragraph (a) of this section shall be furnished to all affected participants and beneficiaries at least 30 days, but not more than 60 days, in advance of the last date on which such participants and beneficiaries could exercise the affected rights immediately before the commencement of any blackout period.

(ii) The requirement to give at least 30 days advance notice contained in paragraph (b)(2)(i) of this section shall not apply in any case in which—

(A) A deferral of the blackout period in order to comply with paragraph (b)(2)(i) of this section would result in a violation of the requirements of section 404(a)(1)(A) or (B) of the Act, and a fiduciary of the plan reasonably so determines in writing;

(B) The inability to provide the advance notice of a blackout period is due to events that were unforeseeable or

circumstances beyond the reasonable control of the plan administrator, and a fiduciary of the plan reasonably so determines in writing; or

(C) The blackout period applies only to one or more participants or beneficiaries solely in connection with their becoming, or ceasing to be, participants or beneficiaries of the plan as a result of a merger, acquisition, divestiture, or similar transaction involving the plan or plan sponsor.

(iii) In any case in which paragraph (b)(2)(ii) of this section applies, the administrator shall furnish the notice described in paragraph (a) of this section to all affected participants and beneficiaries as soon as reasonably possible under the circumstances, unless such notice in advance of the termination of the blackout period is impracticable.

(iv) Determinations under paragraph (b)(2)(ii)(A) and (B) of this section must be dated and signed by the fiduciary.

(3) *Form and manner of furnishing notice.* The notice required by paragraph (a) of this section shall be in writing and furnished to affected participants and beneficiaries in any manner consistent with the requirements of § 2520.104b–1 of this chapter, including paragraph (c) of that section relating to the use of electronic media.

(4) *Changes in length of blackout period.* If, following the furnishing of a notice pursuant to this section, there is a change in the length of the blackout period (specified in such notice pursuant to paragraph (b)(1)(iii) of this section), the administrator shall furnish all affected participants and beneficiaries an updated notice explaining the reasons for the change and identifying all material changes in the information contained in the prior notice. Such notice shall be furnished to all affected participants and beneficiaries as soon as reasonably possible, unless such notice in advance of the termination of the blackout period is impracticable.

(c) *Notice to issuer of employer securities.* (1) The notice required by paragraph (a) of this section shall be furnished to the issuer of any employer securities held by the plan and subject to the blackout period. Such notice shall contain the information described in paragraph (b)(1)(i), (ii), (iii) and (vi) of this section and shall be furnished in accordance with the time frames prescribed in paragraph (b)(2) of this section. In the event of a change in the length of the blackout period specified in such notice, the plan administrator shall furnish an updated notice to the issuer in accordance with the requirements of paragraph (b)(4) of this section.

(2) For purposes of this section, notice to the agent for service of legal process for the issuer shall constitute notice to the issuer, unless the issuer has provided the plan administrator with the name of another person for service of notice, in which case the plan administrator shall furnish notice to such person. Such notice shall be in writing, except that the notice may be in electronic or other form to the extent the person to whom notice must be furnished consents to receive the notice in such form.

(3) If the issuer designates the plan administrator as the person for service of notice pursuant to paragraph (c)(2) of this section, the issuer shall be deemed to have been furnished notice on the same date as notice is furnished to affected participants and beneficiaries pursuant to paragraph (b) of this section.

(d) *Definitions.* For purposes of this section—

(1) *Blackout period*—

(i) *General.* The term ''blackout period'' means, in connection with an individual account plan, any period for which any ability of participants or beneficiaries under the plan, which is otherwise available under the terms of such plan, to direct or diversify assets credited to their accounts, to obtain loans from the plan, or to obtain distributions from the plan is temporarily suspended, limited, or restricted, if such suspension, limitation, or restriction is for any period of more than three consecutive business days.

(ii) *Exclusions.* The term ''blackout period'' does not include a suspension, limitation, or restriction—

(A) Which occurs by reason of the application of the securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934);

(B) Which is a regularly scheduled suspension, limitation, or restriction under the plan (or change thereto), provided that such suspension, limitation or restriction (or change) has been disclosed to affected plan participants and beneficiaries through the summary plan description, a summary of material modifications, materials describing specific investment alternatives under the plan and limits thereon or any changes thereto, participation or enrollment forms, or any other documents and instruments pursuant to which the plan is established or operated that have been furnished to such participants and beneficiaries;

(C) Which occurs by reason of a qualified domestic relations order or by reason of a pending determination (by the plan administrator, by a court of competent jurisdiction or otherwise) whether a domestic relations order filed (or reasonably anticipated to be filed) with the plan is a qualified order within the meaning of section 206(d)(3)(B)(i) of the Act; or

(D) Which occurs by reason of an act or a failure to act on the part of an individual participant or by reason of an action or claim by a party unrelated to the plan involving the account of an individual participant.

(2) *Individual account plan.* The term ''individual account plan'' shall have the meaning provided such term in section 3(34) of the Act, except that such term shall not include a ''one-participant retirement plan'' within the meaning of paragraph (d)(3) of this section.

(3) *One-participant retirement plan.* The term ''one-participant retirement plan'' means a one-participant retirement plan as defined in section 101(i)(8)(B) of the Act.

(4) *Issuer.* The term ''issuer'' means an issuer as defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c), the securities of which are registered under section 12 of the Securities Exchange Act of 1934, or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934, or files or has filed a registration statement that has not yet become effective under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), and that it has not withdrawn.

(5) *Calendar week.* For purposes of paragraph (b)(1)(iii)(B), the term ''calendar week'' means a seven day period beginning on Sunday and ending on Saturday.

(e) *Model notice*—(1) *General.* The model notice set forth in paragraph (e)(2) of this section is intended to assist plan administrators in discharging their notice obligations under this section. Use of the model notice is not mandatory. However, a notice that uses the statements provided in paragraphs 4. and 5.(A) of the model notice will be deemed to satisfy the notice content requirements of paragraph (b)(1)(iv) and (b)(1)(v)(A), respectively, of this section. With regard to all other information required by paragraph (b)(1) of this section, compliance with the notice content requirements will depend on the facts and circumstances pertaining to the particular blackout period and plan.

(2) *Form and content of model notice.*

Important Notice Concerning Your Rights

Under The [Enter Name of Individual Account Plan]

[Enter date of notice]

1. This notice is to inform you that the [enter name of plan] will be [enter reasons for blackout period, as appropriate: changing investment options, changing recordkeepers, etc.].

2. As a result of these changes, you temporarily will be unable to [enter as appropriate: direct or diversify investments in your individual accounts (if only specific investments are subject to the blackout, those investments should be specifically identified), obtain a loan from the plan, or obtain a distribution from the plan]. This period, during which you will be unable to exercise these rights otherwise available under the plan, is called a ''blackout period.'' Whether or not you are planning retirement in the near future, we encourage you to carefully consider how this blackout period may affect your retirement planning, as well as your overall financial plan.

3. The blackout period for the plan [enter the following as appropriate: is expected to begin on [enter date] and end [enter date]/is expected to begin during the week of [enter date] and end during the week of [enter date]. During these weeks, you can determine whether the blackout period has started or ended by [enter instructions for use toll-free number or accessing web site].

4. [*In the case of investments affected by the blackout period, add the following:* During blackout period you will be unable to direct or diversify the assets held in your plan account. For this reason, it is very important that you review and consider the appropriateness of your current investments in light of your inability to direct or diversify those investments during the blackout period. For your long-term retirement security, you should give careful consideration to the importance of a well-balanced and diversified investment portfolio, taking into account all your assets, income and investments.] [If the plan permits investments in individual securities, add the following: You should be aware that there is a risk to holding substantial portions of your assets in the securities of any one company, as individual securities tend to have wider price swings, up and down, in short periods of time, than investments in diversified funds. Stocks that have wide price swings might have a large loss during the blackout period, and you would not be able to direct the sale of such stocks from your account during the blackout period.]

5. [*If timely notice cannot be provided (see paragraph (b)(1)(v) of this section) enter:* (A) Federal law generally requires that you be furnished notice of a blackout period at least 30 days in advance of the last date on which you could exercise your affected rights immediately before the commencement of any blackout period in order to provide you with sufficient time to consider the effect of the blackout period on your retirement and financial plans. (B) [Enter explanation of reasons for inability to furnish 30 days advance notice.]]

6. If you have any questions concerning this notice, you should contact [enter name, address and telephone number of the plan administrator or other contact responsible for answering questions about the blackout period].

(f) *Effective date.* This section shall be effective and shall apply to any blackout period commencing on or after January 26, 2003. For the period January 26, 2003 to February 25, 2003, plan administrators shall furnish notice as soon as reasonably possible.

Dated: January 16, 2003.

Ann L. Combs,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 03–1430 Filed 1–23–03; 8:45 am]

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DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Parts 2560 and 2570

RIN 1210–AA91, RIN 1210–AA93

Civil Penalties Under ERISA Section 502(c)(7) and Conforming Technical Changes on Civil Penalties Under ERISA Sections 502(c)(2), 502(c)(5) and 502(c)(6)

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Final rules.

SUMMARY: This document contains final rules that implement the civil penalty provision in section 502(c)(7) of the Employee Retirement Income Security Act of 1974 (the Act or ERISA) adopted as part of the Sarbanes-Oxley Act of 2002 (SOA). The final rules establish procedures relating to the assessment of civil penalties by the Department of Labor (Department) under section 502(c)(7) of ERISA for failures or refusals by plan administrators to provide notices of a blackout period as required by section 101(i) of ERISA. This document also contains final rules making conforming and technical changes to the agency's rules of practice and procedure for other civil penalties under section 502(c) of ERISA. The final rules affect employee benefit plans, plan sponsors, administrators and fiduciaries, and plan participants and beneficiaries.

DATES: *Effective date:* These final rules are effective January 26, 2003.

FOR FURTHER INFORMATION CONTACT: Susan Elizabeth Rees, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor, Washington, DC 20210, (202) 693–8537 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

A. Background

The Sarbanes-Oxley Act of 2002 (the SOA), Pub. L. 107–204, was enacted on July 30, 2002. Section 306(b)(1) of the SOA amended section 101 of ERISA to add a new subsection (i), requiring that administrators of individual account plans provide notice to affected participants and beneficiaries in advance of the commencement of any blackout period. For purposes of this notice requirement, a blackout period generally includes any period during which the ability of participants or beneficiaries to direct or diversify assets credited to their accounts, to obtain loans from the plan or to obtain distributions from the plan will be temporarily suspended, limited or restricted. Elsewhere in the **Federal Register** today, the Department has published a final rule, to be codified at 29 CFR 2520.101–3, implementing the notice requirements in ERISA section 101(i).

Section 306(b)(3) of SOA amended section 502(c) of ERISA to add a new paragraph (7) establishing a civil penalty for an administrator's failure or refusal to provide timely notice of a blackout period to participants and beneficiaries. Specifically, section 502(c)(7) provides that the Secretary may assess a civil penalty of up to $100 a day from the date of the plan administrator's failure or refusal to provide notice to a participant or beneficiary in accordance with ERISA section 101(i).

On October 21, 2002, the Department published interim rules implementing section 502(c)(7) of ERISA in the **Federal Register** (67 FR 64774) for public comment. The interim rules established procedures relating to the assessment and administrative review of civil penalties by the Department under section 502(c)(7) for failures or refusals by plan administrators to provide notice of a blackout period as required by section 101(i) of ERISA and 29 CFR 2520.101–3. The interim rules also made changes to the existing civil penalty rules under ERISA sections 502(c)(2), 502(c)(5), and 502(c)(6) to incorporate certain technical improvements being adopted as part of the section 502(c)(7) implementing regulations.

The Department received 7 comments on the section 502(c)(7) interim rules in response to its request for comments. Set forth below is an overview of the final rules, which adopt the interim

rules with a technical addition to address the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, and a discussion of the public comments.

B. Overview of Final Rules and Public Comments

1. Assessment of Civil Penalties for Violations of Section 101(i) of ERISA—§ 2560.502c–7

Section 2560.502c–7 addresses the general application of section 502(c)(7) of ERISA, under which the administrator of an individual account plan shall be liable for civil penalties assessed by the Secretary in each case in which there is a failure or refusal to provide to an affected participant or beneficiary notice of a blackout period as required under section 101(i) of ERISA and § 2520.101–3. Section 2560.502c–7 defines terms, sets forth how the maximum penalty amounts are computed, and identifies the period for which a penalty is assessed. The section also sets forth the rule that prior to assessing a penalty under ERISA section 502(c)(7), the Department must provide the plan administrator with written notice of intent to assess a penalty, and provide the administrator with the opportunity to request that a penalty not be assessed upon a showing of compliance with ERISA section 101(i), or be waived, in whole or in part, upon a showing that there were mitigating circumstances justifying a waiver or reduction of the penalty for noncompliance. Section 2560.502c–7 also establishes certain procedural rules regarding deadlines and service requirements in connection with penalty assessment proceedings, and the consequences of failure to comply therewith. The section clarifies the personal liability of the plan administrator for penalties assessed. Specifically, the section provides that, if more than one person is responsible as administrator for the failure to provide the required blackout notice, all such persons shall be jointly and severally liable for such failure, and that the liability is a personal liability of the person against whom the penalty is assessed and not a liability of the plan. Finally, the section provides that the plan administrator has the opportunity to contest the assessment in administrative proceedings governed by Part 2570 of Title 29 of the Code of Federal Regulations, described below.

Several commenters requested that § 2560.502c–7(b)(1) be changed to shorten the maximum period for which a civil penalty may be assessed. Under the interim rule, the amount assessed under section 502(c)(7) for each separate violation is to be determined by the Department, taking into consideration the degree and/or willfulness of the failure or refusal to provide a notice of blackout period. The rule further provides that the maximum amount assessed for each violation shall not exceed $100 a day,[1] computed from the date of the administrator's failure or refusal to provide a notice of blackout period up to and including the date that is the final day of the blackout period for which the notice was required. The interim rule defines a failure or refusal to provide a notice of blackout period to mean a failure or refusal to provide notice of a blackout period to an affected plan participant or beneficiary at the time and in the manner prescribed by section 101(i) of the Act and § 2520.101–3. For purposes of calculating the amount to be assessed, a failure or refusal to provide a notice of blackout period with respect to any single participant or beneficiary is treated as a separate violation under section 101(i) of the Act and § 2520.101–3.

In general, the commenters requested that the rule be amended to provide that the penalty would only apply to the extent that a notice is late, *i.e.*, only days prior to the date on which notice is actually given would be counted in determining the penalty, and that the penalty calculation period would run to the end of the blackout period only in cases where no notice is provided. The commenters expressed concern that the interim rule exposes plan administrators who make a good faith effort to comply to potentially substantial penalties even in cases where the blackout notice is only one or two days late. These commenters suggested that their proposed change would give plan administrators an incentive to provide the notice as quickly as possible, even if late.

The blackout notice requirements are intended to ensure that plan participants and beneficiaries are afforded advance notice of plan imposed restrictions on their rights in order that they may take appropriate steps in anticipation of the restriction. The SOA expressly provides in section 502(c)(7) that the beginning date for calculating the penalty is the date of the administrator's failure or refusal to provide a notice of blackout period, but does not, however, specify an ending date for the penalty calculation. In adding section 101(i) to Title I of ERISA, the SOA established a 30-days advance notice requirement and listed exceptions to that general rule where less than 30 days notice was permitted. Failure to provide a timely blackout notice, therefore, serves to deprive affected participants and beneficiaries of the full period of time Congress concluded was the minimum period necessary for those individuals to sufficiently consider effects of the blackout period on their investments and financial plans. Accordingly, providing participants and beneficiaries a late notice does not serve to correct the violation. Moreover, the situations in which penalties are most likely to be assessed in this area are those where it already has been determined that the failure is not due to events that were unforeseeable or beyond the control of the plan administrator, nor due to avoiding a breach of fiduciary responsibility.

In connection with a failure to provide timely notice, when an administrator provides notice would be one factor to be taken into account in determining the degree or willfulness of a violation. In this regard, the Department would, for example, also take into account the feasibility of delaying the blackout period so as to provide the required advance notice, the length of time between the late issuance and the beginning of the blackout period, the effect of the lateness on the ability of affected participants and beneficiaries to take appropriate steps in anticipation of the restriction, actions implemented by the administrator to ameliorate adverse effects on participants and beneficiaries, and the length of the blackout period itself. Further, the Department notes that the ability of administrators to submit statements of reasonable cause (§ 2560.502c–7(e)) and to appeal civil penalty determinations (§ 2560.502c–7(h)) under the final rules ensures that administrators have the opportunity to pursue waivers or reductions of penalty amounts.

Several commenters sought clarification regarding whether the Department would waive penalties under § 2560.502c–7(d) in cases

[1] As discussed in more detail in a following section of this preamble, this document also contains a technical amendment to section § 2560.502c–7(b) designed to reflect the requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), Pub. L. 101–410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996 (the Act), Pub. L. 104–134, 110 Stat. 1321–373. The Act amended the 1990 Act to require generally that federal agencies adjust certain civil monetary penalties for inflation no later than 180 days after the enactment of the Act, and at least once every four years thereafter, in accordance with the guidelines specified in the 1990 Act. The Act specifies that any such increase in a civil monetary penalty shall apply only to violations that occur after the date the increase takes effect.

involving inadvertent and minor violations. For example, one commenter suggested that the rule be clarified to indicate that civil penalties will not be assessed if a plan administrator, acting reasonably and in good faith, inadvertently fails to furnish a timely blackout notice to a small percentage of those entitled to receive the notice. Another commenter suggested that mistakes, such as misaddressed envelopes, misspelled names, especially occurring as the new blackout notification procedures are implemented, should be dealt with leniently where the errors are inadvertent and/or de minimus. Another commenter suggested that a plan administrator who makes reasonable good faith efforts to provide notices and who promptly corrects any failure that is brought to its attention should not be penalized.

As noted above, decisions regarding a waiver or reduction of penalty assessments will take into account a variety of factors on the facts and circumstances involved in each case. For this reason, it is not feasible to list specific criteria in the regulation that would be treated as mitigating circumstances in every case. Although, as also noted above, the Department will consider whether administrators acted reasonably and in good faith, and whether mistakes were inadvertent and promptly addressed, the provision in the interim rule allowing administrators to make showings regarding the ''degree and/or willfulness'' of the violation gives ample opportunity for extenuating circumstances to be raised and considered in the penalty assessment proceedings.

Another commenter requested clarification regarding how the Department will apply § 2560.502c–7(j), which provides that, ''if more than one person is responsible as administrator for the failure to provide a notice of blackout period * * * all such persons shall be jointly and severally liable for such failure.'' Section 502(c)(7) states that the civil penalty is assessable against a ''plan administrator.'' As the Department stated in the preamble to its parallel final rule, to be codified at 29 CFR 2520.101–3, implementing the notice requirements in ERISA section 101(i), references to plan administrator and administrator mean the ''administrator'' as defined in section 3(16)(A) of ERISA. In that regard, section 2560.502c–7(a)(1) expressly provides that ''the administrator (within the meaning of section 3(16)(A) of the Act) of an individual account plan * * * shall be liable for civil penalties assessed by the Secretary under section 502(c)(7) * * *'' The joint and several liability provision in § 2560.502c–7(j) is intended to make it clear that where the administrator is more than one person, *e.g.*, a committee, joint board, or other group of individuals, each person may be held separately liable for a notice violation under the civil penalty regulation.

One commenter suggested that the regulation be amended to include a one-year limit from the date a blackout period commences on the Department's ability to issue a notice of intent to assess civil penalties under section 502(c)(7). The Department notes that there is nothing in Title I of ERISA that establishes such a time limit on the Department's ability to assess civil penalties under section 502(c)(7), or under any of the other provisions of section 502(c) pursuant to which the Department has the authority to assess civil penalties for violations of Title I of ERISA. Accordingly, the Department does not believe it would be appropriate to adopt such a time limit as part of this rulemaking.

The same commenter also expressed concern that § 2560.502c–7(f) was ''harsh'' in providing that an administrator who fails to respond to a notice of intent to assess a penalty will be deemed to have admitted the facts alleged in the notice and waived the right to appear and contest the penalty assessment. A similar default provision applies in connection with the Department's other civil penalty proceedings under section 502(c) of the Act, and it is designed to ensure the Secretary's ability to effectively enforce section 502(c) of ERISA. Accordingly, the Department is not making any change to this provision in the final rule.

One commenter expressed concern about the assessment of substantial civil penalties for violations of the notice required to be provided by the administrator to the issuer under section 101(i)(2)(E) of ERISA in cases where the plan administrator is the issuer or an affiliate. The Department notes that section 502(c)(7) provides for a penalty to be assessed against a plan administrator for a ''failure or refusal to provide notice to participants and beneficiaries in accordance with section 101(i).'' In the Department's view, the section 502(c)(7) penalty is not applicable for failures to provide the notice to issuers required under section 101(i)(2)(E).

2. Procedures for Administrative Review of Assessment of Civil Penalties Under ERISA Section 502(c)(7)—§ 2570.130 et seq.

The interim rules added to part 2570, Subpart G, section 2570.130 through section 2570.141, to establish procedures for hearings before an Administrative Law Judge (ALJ) with respect to assessment by the Department of a civil penalty under ERISA section 502(c)(7), and for appealing an ALJ decision to the Secretary or his or her delegate. With regard to such procedures, the Secretary has established the Pension and Welfare Benefits Administration (PWBA) within the Department for purposes of carrying out most of the Secretary's responsibilities under ERISA. See Secretary's Order 1–87, 52 FR 13139 (April 27, 1987). The Department received no comments on these procedural rules, and, therefore, the final rules are issued without change from the interim rules.

3. Conforming Changes to Existing Civil Penalties Rules Under ERISA Sections 502(c)(2), 502(c)(5) and 502(c)(6)—§§ 2560.502c–2, 2560.502c–5, 2560.502c–6, and Subparts C, E, and F of Part 2570

The interim rules also amended the existing civil penalty assessment regulations under ERISA sections 502(c)(2), 502(c)(5) and 502(c)(6) in part 2560 and in Part 2570 of subchapter G, to conform them to the rules of practice and procedure being adopted for penalty proceedings under ERISA section 502(c)(7) in 29 CFR 2560.502c–7 and part 2570 Subpart G. The amendments affect certain rules for penalty assessment and administrative review in § 2560.502c–2, § 2560.502c–5, § 2560.502c–6, and subparts C, E, and F of Part 2570. The primary amendments were intended to conform the filing and service rules under § 2560.502c–2, § 2560.502c–5 and § 2560.502c–6 to those being adopted for proceedings under § 2560.502c–7. In addition, §§ 2560.502c–2(d) and (e), §§ 2560.502c–5(d) and (e), and §§ 2560.502c–6(d) and (e) were amended to use the clarifying language adopted in §§ 2560.502c–7(d) and (e) that better describes the statement of reasonable cause and penalty waiver procedures.

The Department received no comments in response to its request for comments on the conforming technical amendments to § 2560.502c–2, § 2560.502c–5, § 2560.502c–6, and subparts C, E, and F of Part 2570 which were adopted in the interim rule.

Therefore, except for the technical changes noted below intended to address the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, the interim rules are being adopted as final rules without change.

4. Technical Changes to §§ 2560.502c–2(b), 2560.502c–5(b), 2560.502c–6(b), 2560.502c–7(b), To Reflect the Requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990, as Amended

This document also contains technical amendments to § 2560.502c–2(b), § 2560.502c–5(b), § 2560.502c–6(b), and § 2560.502c–7(b), regarding the maximum penalty amounts that may be assessed. The amendments are designed to reflect the requirements of the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Act), Pub. L. 101–410, 104 Stat. 890, as amended by the Debt Collection Improvement Act of 1996 (the Act), Pub. L. 104–134, 110 Stat. 1321–373. The Act amended the 1990 Act to require generally that federal agencies adjust certain civil monetary penalties for inflation no later than 180 days after the enactment of the Act, and at least once every four years thereafter, in accordance with the guidelines specified in the 1990 Act, as amended. The Act specifies that any such increase in a civil monetary penalty shall apply only to violations that occur after the date the increase takes effect. The Department's civil monetary penalty inflation adjustment regulations are codified in part 2575 of Title 29 of the Code of Federal Regulations.[2] The technical amendments to § 2560.502c–2(b), § 2560.502c–5(b), § 2560.502c–6(b), and § 2560.502c–7(b) in this document are being made under section 505 of ERISA which authorizes the Department to prescribe such regulations as the Secretary finds necessary or appropriate to carry out the provisions of Title I of ERISA. As a general matter, the Administrative Procedure Act (APA) requires rulemakings to be published in the **Federal Register** and also mandates that an opportunity for comments be provided when an agency promulgates regulations. Section 553(b)(3)(B) of the APA exempts certain rules or agency procedures from the notice and comment requirements when an agency finds for good cause that notice and public comment are impracticable, unnecessary, or contrary to the public interest. The Department finds for good cause that notice and comment on these technical amendments to § 2560.502c–2(b), § 2560.502c–5(b), § 2560.502c–6(b), and § 2560.502c–6(b) is unnecessary. The amendments merely confirm that the maximum amount of the civil penalty assessable by the Department under its implementing regulations is the maximum amount stated in sections 502(c)(2), 502(c)(5), 502(c)(6), and 502(c)(7), or such other maximum amount as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended. Accordingly, the Secretary determined that these technical changes were appropriate to issue in final form.

5. Effective Date

These final rules are effective January 26, 2003. The final rules establishing procedures relating to the assessment of civil penalties by the Department under section 502(c)(7) of ERISA shall apply to failures or refusals by plan administrators to provide notices of a blackout period as required by section 101(i) of ERISA and 29 CFR 2520.101–3 on or after that date. Pursuant to section 553(c) of the APA, the Department finds good cause for these rules to be effective less than 30 days after publication. The Department believes that having the blackout notice civil penalty rules effective on the effective date of the underlying statutory provisions will avoid confusion for plan administrators, and the amendments to the existing civil penalty rules under ERISA sections 502(c)(2), 502(c)(5), and 502(c)(6) merely incorporate certain technical improvements being adopted as part of the section 502(c)(7) implementing regulations. Moreover, the limited extent of the differences between the instant rule and the interim rules will minimize any difficulties in complying with these rules by the effective date.

C. Regulatory Impact Analysis

Executive Order 12866

Under Executive Order 12866 (58 FR 51735), the Department must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. The Department has determined that these final rules relating to the assessment of civil monetary penalties under section 502(c)(7) of ERISA are significant in that they provide guidance on the administration and enforcement of the notice provisions of section 101(i) of ERISA. Separate guidance on the notice requirements of section 101(i) (Final Rule Relating to Notice of Blackout Periods to Participants and Beneficiaries), also published in today's issue of the **Federal Register**, is also considered significant within the meaning of section 3(f)(4) of the Executive Order. Accordingly, OMB has reviewed the final rules pertaining to both the blackout notice and the related civil penalty pursuant to the terms of the Executive Order.

The principal benefit of the statutory penalty provisions and these final rules will be greater adherence to the requirement of ERISA section 101(i) that plan administrators provide advance written notice to participants and beneficiaries in individual account retirement plans whose existing rights to direct investments in their accounts or to obtain loans or distributions will be suspended or limited. The implementation of orderly and consistent processes for the assessment of penalties and the review of such assessments will also be beneficial for plan administrators. The procedures established in these final rules will also allow facts and circumstances related to a failure or refusal to provide appropriate notice to be presented by a plan administrator and to be taken into consideration by the Department in assessing penalties under ERISA section 502(c)(7).

[2] The Department will be publishing shortly a separate final rule implementing the required inflation adjustment for this adjustment cycle. Application of the required methodology will result in a small increase in only two Title I civil penalty amounts. Specifically, the civil monetary penalty set by ERISA section 502(c)(5) for a failure or refusal on the part of certain administrators to file Form M–1 information with the Department as required by ERISA section 101(g) will be adjusted from $1,000 to $1,100 per day, and the civil monetary penalty set by ERISA section 502(c)(6) for a failure on the part of the plan administrator to furnish certain plan documents to the Secretary on request will be adjusted from $100 to $110 per day with the penalty cap being adjusted from $1,000 to $1,100 per request. No adjustments were required for any other civil penalties under Title I of ERISA.

The rate of failure or refusal to provide blackout notices where required, and the dollar value of penalties to be assessed in those cases cannot be predicted. The civil penalty provisions of the statute and these final rules impose no mandatory requirements or costs, except where a plan administrator has failed to provide the notice required in ERISA section 101(i).

The technical amendments conforming the existing regulatory provisions relating to the assessment of civil penalties under sections 502(c)(2), (c)(5), and (c)(6) of ERISA are procedural in nature, and similarly impose no additional requirements or costs.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. For purposes of its analyses under the RFA, PWBA continues to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reporting for pension plans that cover fewer than 100 participants. Because this guidance was originally issued an interim final rule pursuant to the authority and deadlines prescribed in sections 306(b)(2) of SOA, RFA does not apply, and regulatory flexibility analysis is not required. However, in the interim final rule, the Department requested comments regarding any special issues facing small plans, or any alternative approaches that would assist small plans with compliance with respect to the assessment of civil penalties under ERISA section 502(c)(7) and the conforming amendments to existing administrative and procedural regulations relating to the assessment of civil penalties under ERISA sections 502(c)(2), (c)(5), and (c)(6). No such comments were received.

The terms of the statute pertaining to the assessment of civil penalties for failure to provide notices to plan participants and beneficiaries in the event of a blackout do not vary relative to plan or plan administrator size. The operation of the statute will normally result in the assessment of lower penalties where small plans are involved because a violation with respect to a single participant or beneficiary is treated as a separate violation for purposes of calculating the penalty. The opportunity for a plan administrator to present facts and circumstances related to a failure or refusal to provide appropriate notice that may be taken into consideration by the Department in assessing penalties under ERISA section 502(c)(7) may offer some degree of flexibility to small entities subject to penalty assessments. Penalty assessments will have no direct impact on small plans because the plan administrator assessed a civil penalty is personally liable for the payment of that penalty pursuant to section 2560.502c–7(j).

Paperwork Reduction Act

This Final Rule on Assessment of Civil Penalties under ERISA section 502(c)(7) is not subject to the requirements of the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3501 *et seq.*) because it does not contain a collection of information as defined in 44 U.S.C. 3502(3). Information otherwise provided to the Secretary in connection with the administrative and procedural requirements of these final rules is excepted from coverage by PRA 95 pursuant to 44 U.S.C. 3518(c)(1)(B), and related regulations at 5 CFR 1320.4(a)(2) and (c). These provisions generally except information provided as a result of an agency's civil or administrative action, investigation, or audit. This exception also applies to the conforming amendments to administrative and procedural rules pertaining to the civil penalty provisions of ERISA sections 502(c)(2), 502(c)(5), and 502(c)(6).

Congressional Review Act

The rules being issued here are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review. The rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, and does not impose an annual burden exceeding $100 million on the private sector.

Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of 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. These final rules do not have federalism implications because it has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in these final rules do not alter the fundamental reporting and disclosure, or administration and enforcement provisions of the statute with respect to employee benefit plans, and as such have no implications for the States or the relationship or distribution of power between the national government and the States.

List of Subjects

29 CFR Part 2560

Employee benefit plans, Employee Retirement Income Security Act, Law enforcement, Pensions.

29 CFR Part 2570

Administrative practice and procedure, Employee benefit plans, Employee Retirement Income Security Act, Law enforcement, Pensions.

In view of the foregoing, Parts 2560 and 2570 of Chapter XXV of title 29 of the Code of Federal Regulations are amended as follows:

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

1. The authority citation for Part 2560 continues to read as follows:

Authority: 29 U.S.C. 1132, 1135, and Secretary's Order 1–87, 52 FR 13139 (April 21, 1987).

Section 2560.503–1 also issued under 29 U.S.C. 1133.

Section 2560.502(c)(7) also issued under sec. 306 (b)(2) of Pub. L. 107–204, 116 Stat. 745.

2. Revise § 2560.502c–2, paragraphs (b)(1), (d), (e), (f), (g), (h), and (i) to read as follows:

§ 2560.502c–2 Civil penalties under section 502(c)(2).

* * * * *

(b) *Amount assessed.* (1) The amount assessed under section 502(c)(2) of the Act shall be determined by the Department of Labor, taking into consideration the degree and/or willfulness of the failure or refusal to file the annual report. However, the amount assessed under section 502(c)(2) of the Act shall not exceed $1,000 a day (or such other maximum amount as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended), computed from the date of the administrator's failure or refusal to file the annual report and, except as provided in paragraph (b)(2) of this section, continuing up to the date on which an annual report satisfactory to the Secretary is filed.

* * * * *

(d) *Reconsideration or waiver of penalty to be assessed.* The Department may determine that all or part of the penalty amount in the notice of intent to assess a penalty shall not be assessed on a showing that the administrator complied with the requirements of section 101(b)(1) of the Act or on a showing by the administrator of mitigating circumstances regarding the degree or willfulness of the noncompliance.

(e) *Showing of reasonable cause.* Upon issuance by the Department of a notice of intent to assess a penalty, the administrator shall have thirty (30) days from the date of service of the notice, as described in paragraph (i) of this section, to file a statement of reasonable cause explaining why the penalty, as calculated, should be reduced, or not be assessed, for the reasons set forth in paragraph (d) of this section. Such statement must be made in writing and set forth all the facts alleged as reasonable cause for the reduction or nonassessment of the penalty. The statement must contain a declaration by the administrator that the statement is made under the penalties of perjury.

(f) *Failure to file a statement of reasonable cause.* Failure of an administrator to file a statement of reasonable cause within the thirty (30) day period described in paragraph (e) of this section shall be deemed to constitute a waiver of the right to appear and contest the facts alleged in the notice of intent, and such failure shall be deemed an admission of the facts alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(2) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.61(g) of this chapter, forty-five (45) days from the date of service of the notice.

(g) *Notice of the determination on statement of reasonable cause.* (1) The Department, following a review of all the facts alleged in support of no assessment or a complete or partial waiver of the penalty, shall notify the administrator, in writing, of its determination to waive the penalty, in whole or in part, and/or assess a penalty. If it is the determination of the Department to assess a penalty, the notice shall indicate the amount of the penalty, not to exceed the amount described in paragraph (c) of this section. This notice is a ''pleading'' for purposes of § 2570.61(m) of this chapter.

(2) Except as provided in paragraph (h) of this section, a notice issued pursuant to paragraph (g)(1) of this section, indicating the Department's intention to assess a penalty, shall become a final order, within the meaning of § 2570.61(g) of this chapter, forty-five (45) days from the date of service of the notice.

(h) *Administrative hearing.* A notice issued pursuant to paragraph (g) of this section will not become a final order, within the meaning of § 2570.61(g) of this chapter, if, within thirty (30) days from the date of the service of the notice, the administrator or a representative thereof files a request for a hearing under §§ 2570.60 through 2570.71 of this chapter, and files an answer to the notice. The request for hearing and answer must be filed in accordance with § 2570.62 of this chapter and § 18.4 of this title. The answer opposing the proposed sanction shall be in writing, and supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to paragraph (g) of this section.

(i) *Service of notices and filing of statements.* (1) Service of a notice for purposes of paragraphs (c) and (g) of this section shall be made:

(i) By delivering a copy to the administrator or representative thereof;

(ii) By leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or

(iii) By mailing a copy to the last known address of the administrator or representative thereof.

(2) If service is accomplished by certified mail, service is complete upon mailing. If service is by regular mail, service is complete upon receipt by the addressee. When service of a notice under paragraph (c) or (g) of this section is by certified mail, five (5) days shall be added to the time allowed by these rules for the filing of a statement, or a request for hearing and answer, as applicable.

(3) For purposes of this section, a statement of reasonable cause shall be considered filed:

(i) Upon mailing, if accomplished using United States Postal Service certified mail or Express Mail;

(ii) Upon receipt by the delivery service, if accomplished using a ''designated private delivery service'' within the meaning of 26 U.S.C. 7502(f);

(iii) Upon transmittal, if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment; or

(iv) In the case of any other method of filing, upon receipt by the Department at the address provided in the notice of intent to assess a penalty.

* * * * *

3. Revise § 2560.502c–5, paragraphs (b)(1), (d), (e), (f), (g), (h), and (i) to read as follows:

§ 2560.502c–5 Civil penalties under section 502(c)(5).

* * * * *

(b) *Amount assessed.* (1) The amount assessed under section 502(c)(5) of the Act shall be determined by the Department of Labor, taking into consideration the degree and/or willfulness of the failure or refusal to file the report. However, the amount assessed under section 502(c)(5) of the Act shall not exceed $1,000 a day (or such other maximum amount as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended), computed from the date of the administrator's failure or refusal to file the report and, except as provided in paragraph (b)(2) of this section, continuing up to the date on which a report meeting the requirements of

section 101(g) and § 2520.101–2, as determined by the Secretary, is filed.

* * * * *

(d) *Reconsideration or waiver of penalty to be assessed.* The Department may determine that all or part of the penalty amount in the notice of intent to assess a penalty shall not be assessed on a showing that the administrator complied with the requirements of section 101(g) of the Act or on a showing by the administrator of mitigating circumstances regarding the degree or willfulness of the noncompliance.

(e) *Showing of reasonable cause.* Upon issuance by the Department of a notice of intent to assess a penalty, the administrator shall have thirty (30) days from the date of service of the notice, as described in paragraph (i) of this section, to file a statement of reasonable cause explaining why the penalty, as calculated, should be reduced, or not be assessed, for the reasons set forth in paragraph (d) of this section. Such statement must be made in writing and set forth all the facts alleged as reasonable cause for the reduction or nonassessment of the penalty. The statement must contain a declaration by the administrator that the statement is made under the penalties of perjury.

(f) *Failure to file a statement of reasonable cause.* Failure of an administrator to file a statement of reasonable cause within the thirty (30) day period described in paragraph (e) of this section shall be deemed to constitute a waiver of the right to appear and contest the facts alleged in the notice of intent, and such failure shall be deemed an admission of the facts alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(5) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.91(g) of this chapter, forty-five (45) days from the date of service of the notice.

(g) *Notice of the determination on statement of reasonable cause.* (1) The Department, following a review of all the facts alleged in support of no assessment or a complete or partial waiver of the penalty, shall notify the administrator, in writing, of its determination to waive the penalty, in whole or in part, and/or assess a penalty. If it is the determination of the Department to assess a penalty, the notice shall indicate the amount of the penalty, not to exceed the amount described in paragraph (c) of this section, and a brief statement of the reasons for assessing the penalty. This notice is a ''pleading'' for purposes of § 2570.91(m) of this chapter.

(2) Except as provided in paragraph (h) of this section, a notice issued pursuant to paragraph (g)(1) of this section, indicating the Department's intention to assess a penalty, shall become a final order, within the meaning of § 2570.91(g) of this chapter, forty-five (45) days from the date of service of the notice.

(h) *Administrative hearing.* A notice issued pursuant to paragraph (g) of this section will not become a final order, within the meaning of § 2570.91(g) of this chapter, if, within thirty (30) days from the date of the service of the notice, the administrator or a representative thereof files a request for a hearing under §§ 2570.90 through 2570.101 of this chapter, and files an answer to the notice. The request for hearing and answer must be filed in accordance with § 2570.92 of this chapter and § 18.4 of this title. The answer opposing the proposed sanction shall be in writing, and supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to paragraph (g) of this section.

(i) *Service of notices and filing of statements.* (1) Service of a notice for purposes of paragraphs (c) and (g) of this section shall be made:

(i) By delivering a copy to the administrator or representative thereof;

(ii) By leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or

(iii) By mailing a copy to the last known address of the administrator or representative thereof.

(2) If service is accomplished by certified mail, service is complete upon mailing. If service is by regular mail, service is complete upon receipt by the addressee. When service of a notice under paragraph (c) or (g) of this section is by certified mail, five (5) days shall be added to the time allowed by these rules for the filing of a statement, or a request for hearing and answer, as applicable.

(3) For purposes of this section, a statement of reasonable cause shall be considered filed:

(i) Upon mailing, if accomplished using United States Postal Service certified mail or Express Mail;

(ii) Upon receipt by the delivery service, if accomplished using a ''designated private delivery service'' within the meaning of 26 U.S.C. 7502(f);

(iii) Upon transmittal, if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment; or

(iv) In the case of any other method of filing, upon receipt by the Department at the address provided in the notice of intent to assess a penalty.

* * * * *

4. Revise § 2560.502c–6, paragraphs (b)(1), (d), (e), (f), (g), (h), and (i) to read as follows:

§ 2560.502c–6 Civil penalties under section 502(c)(6).

* * * * *

(b) *Amount assessed.* (1) The amount assessed under section 502(c)(6) of the Act shall be determined by the Department of Labor, taking into consideration the degree and/or willfulness of the failure or refusal to furnish any document or documents requested by the Department under section 104(a)(6) of the Act. However, the amount assessed under section 502(c)(6) of the Act shall not exceed $100 a day or $1,000 per request (or such other maximum amounts as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended), computed from the date of the administrator's failure or refusal to furnish any document or documents requested by the Department.

* * * * *

(d) *Reconsideration or waiver of penalty to be assessed.* The Department may determine that all or part of the penalty amount in the notice of intent to assess a penalty shall not be assessed on a showing that the administrator complied with the requirements of section 104(a)(6) of the Act or on a showing by the administrator of mitigating circumstances regarding the degree or willfulness of the noncompliance.

(e) *Showing of reasonable cause.* Upon issuance by the Department of a notice of intent to assess a penalty, the administrator shall have thirty (30) days from the date of service of the notice, as described in paragraph (i) of this section, to file a statement of reasonable cause explaining why the penalty, as calculated, should be reduced or not be assessed, for the reasons set forth in paragraph (d) of this section. Such statement must be made in writing and set forth all the facts alleged as reasonable cause for the reduction or nonassessment of the penalty. The statement must contain a declaration by the administrator that the statement is made under the penalties of perjury.

(f) *Failure to file a statement of reasonable cause.* Failure to file a statement of reasonable cause within the 30 day period described in paragraph (e)

of this section shall be deemed to constitute a waiver of the right to appear and contest the facts alleged in the notice of intent, and such failure shall be deemed an admission of the facts alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(6) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.111(g) of this chapter, forty-five (45) days from the date of service of the notice.

(g) *Notice of determination on statement of reasonable cause.* (1) The Department, following a review of all of the facts alleged in support of no assessment or a complete or partial waiver of the penalty, shall notify the administrator, in writing, of its determination not to assess or to waive the penalty, in whole or in part, and/or assess a penalty. If it is the determination of the Department to assess a penalty, the notice shall indicate the amount of the penalty, not to exceed the amount described in paragraph (c) of this section. This notice is a ''pleading'' for purposes of § 2570.111(m) of this chapter.

(2) Except as provided in paragraph (h) of this section, a notice issued pursuant to paragraph (g)(1) of this section, indicating the Department's intention to assess a penalty, shall become a final order, within the meaning of § 2570.111(g) of this chapter, forty-five (45) days from the date of service of the notice.

(h) *Administrative hearing.* A notice issued pursuant to paragraph (g) of this section will not become a final order, within the meaning of § 2570.91(g) of this chapter, if, within thirty (30) days from the date of the service of the notice, the administrator or a representative thereof files a request for a hearing under §§ 2570.110 through 2570.121 of this chapter, and files an answer to the notice. The request for hearing and answer must be filed in accordance with § 2570.112 of this chapter and § 18.4 of this title. The answer opposing the proposed sanction shall be in writing, and supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to paragraph (g) of this section.

(i) *Service of notices and filing of statements.* (1) Service of a notice for purposes of paragraphs (c) and (g) of this section shall be made:

(i) By delivering a copy to the administrator or representative thereof;

(ii) By leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or

(iii) By mailing a copy to the last known address of the administrator or representative thereof.

(2) If service is accomplished by certified mail, service is complete upon mailing. If service is by regular mail, service is complete upon receipt by the addressee. When service of a notice under paragraph (c) or (g) of this section is by certified mail, five (5) days shall be added to the time allowed by these rules for the filing of a statement, or a request for hearing and answer, as applicable.

(3) For purposes of this section, a statement of reasonable cause shall be considered filed:

(i) Upon mailing, if accomplished using United States Postal Service certified mail or Express Mail;

(ii) Upon receipt by the delivery service, if accomplished using a ''designated private delivery service'' within the meaning of 26 U.S.C. 7502(f);

(iii) Upon transmittal, if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment; or

(iv) In the case of any other method of filing, upon receipt by the Department at the address provided in the notice of intent to assess a penalty.

* * * * *

5. Revise § 2560.502c–7 to read as follows:

§ 2560.502c–7 Civil penalties under section 502(c)(7).

(a) *In general.* (1) Pursuant to the authority granted the Secretary under section 502(c)(7) of the Employee Retirement Income Security Act of 1974, as amended (the Act), the administrator (within the meaning of section 3(16)(A) of the Act) of an individual account plan (within the meaning of section 101(i)(8) of the Act and § 2520.101–3(d)(2) of this chapter), shall be liable for civil penalties assessed by the Secretary under section 502(c)(7) of the Act for failure or refusal to provide notice of a blackout period to affected participants and beneficiaries in accordance with section 101(i) of the Act and § 2520.101–3 of this chapter.

(2) For purposes of this section, a failure or refusal to provide a notice of blackout period shall mean a failure or refusal, in whole or in part, to provide notice of a blackout period to an affected plan participant or beneficiary at the time and in the manner prescribed by section 101(i) of the Act and § 2520.101–3 of this chapter.

(b) *Amount assessed.* (1) The amount assessed under section 502(c)(7) of the Act for each separate violation shall be determined by the Department of Labor, taking into consideration the degree and/or willfulness of the failure or refusal to provide a notice of blackout period. However, the amount assessed for each violation under section 502(c)(7) of the Act shall not exceed $100 a day (or such other maximum amount as may be established by regulation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended), computed from the date of the administrator's failure or refusal to provide a notice of blackout period up to and including the date that is the final day of the blackout period for which the notice was required.

(2) For purposes of calculating the amount to be assessed under this section, a failure or refusal to provide a notice of blackout period with respect to any single participant or beneficiary shall be treated as a separate violation under section 101(i) of the Act and § 2520.101–3 of this chapter.

(c) *Notice of intent to assess a penalty.* Prior to the assessment of any penalty under section 502(c)(7) of the Act, the Department shall provide to the administrator of the plan a written notice indicating the Department's intent to assess a penalty under section 502(c)(7) of the Act, the amount of such penalty, the number of participants and beneficiaries on which the penalty is based, the period to which the penalty applies, and the reason(s) for the penalty.

(d) *Reconsideration or waiver of penalty to be assessed.* The Department may determine that all or part of the penalty amount in the notice of intent to assess a penalty shall not be assessed on a showing that the administrator complied with the requirements of section 101(i) of the Act or on a showing by the administrator of mitigating circumstances regarding the degree or willfulness of the noncompliance.

(e) *Showing of reasonable cause.* Upon issuance by the Department of a notice of intent to assess a penalty, the administrator shall have thirty (30) days from the date of service of the notice, as described in paragraph (i) of this section, to file a statement of reasonable cause explaining why the penalty, as calculated, should be reduced, or not be assessed, for the reasons set forth in paragraph (d) of this section. Such statement must be made in writing and set forth all the facts alleged as reasonable cause for the reduction or nonassessment of the penalty. The statement must contain a declaration by the administrator that the statement is made under the penalties of perjury.

(f) *Failure to file a statement of reasonable cause.* Failure to file a statement of reasonable cause within the

30 day period described in paragraph (e) of this section shall be deemed to constitute a waiver of the right to appear and contest the facts alleged in the notice of intent, and such failure shall be deemed an admission of the facts alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(7) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.131(g) of this chapter, forty-five (45) days from the date of service of the notice.

(g) *Notice of determination on statement of reasonable cause.* (1) The Department, following a review of all of the facts in a statement of reasonable cause alleged in support of no assessment or a complete or partial waiver of the penalty, shall notify the administrator, in writing, of its determination on the statement of reasonable cause and its determination whether to waive the penalty in whole or in part, and/or assess a penalty. If it is the determination of the Department to assess a penalty, the notice shall indicate the amount of the penalty assessment, not to exceed the amount described in paragraph (c) of this section. This notice is a ''pleading'' for purposes of § 2570.131(m) of this chapter.

(2) Except as provided in paragraph (h) of this section, a notice issued pursuant to paragraph (g)(1) of this section, indicating the Department's determination to assess a penalty, shall become a final order, within the meaning of § 2570.131(g) of this chapter, forty-five (45) days from the date of service of the notice.

(h) *Administrative hearing.* A notice issued pursuant to paragraph (g) of this section will not become a final order, within the meaning of § 2570.131(g) of this chapter, if, within thirty (30) days from the date of the service of the notice, the administrator or a representative thereof files a request for a hearing under §§ 2570.130 through 2570.141 of this chapter, and files an answer to the notice. The request for hearing and answer must be filed in accordance with § 2570.132 of this chapter and § 18.4 of this title. The answer opposing the proposed sanction shall be in writing, and supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to paragraph (g) of this section.

(i) *Service of notices and filing of statements.* (1) Service of a notice for purposes of paragraphs (c) and (g) of this section shall be made:

(i) By delivering a copy to the administrator or representative thereof;

(ii) By leaving a copy at the principal office, place of business, or residence of the administrator or representative thereof; or

(iii) By mailing a copy to the last known address of the administrator or representative thereof.

(2) If service is accomplished by certified mail, service is complete upon mailing. If service is by regular mail, service is complete upon receipt by the addressee. When service of a notice under paragraph (c) or (g) of this section is by certified mail, five (5) days shall be added to the time allowed by these rules for the filing of a statement or a request for hearing and answer, as applicable.

(3) For purposes of this section, a statement of reasonable cause shall be considered filed:

(i) Upon mailing, if accomplished using United States Postal Service certified mail or Express Mail;

(ii) Upon receipt by the delivery service, if accomplished using a ''designated private delivery service'' within the meaning of 26 U.S.C. 7502(f);

(iii) Upon transmittal, if transmitted in a manner specified in the notice of intent to assess a penalty as a method of transmittal to be accorded such special treatment; or

(iv) In the case of any other method of filing, upon receipt by the Department at the address provided in the notice of intent to assess a penalty.

(j) *Liability.* (1) If more than one person is responsible as administrator for the failure to provide a notice of blackout period under section 101(i) of the Act and its implementing regulations (§ 2520.101–3 of this chapter), all such persons shall be jointly and severally liable for such failure.

(2) Any person, or persons under paragraph (j)(1) of this section, against whom a civil penalty has been assessed under section 502(c)(7) of the Act, pursuant to a final order, within the meaning of § 2570.131(g) of this chapter, shall be personally liable for the payment of such penalty.

(k) *Cross-reference.* See §§ 2570.130 through 2570.141 of this chapter for procedural rules relating to administrative hearings under section 502(c)(7) of the Act.

PART 2570—PROCEDURAL REGULATIONS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT

6. The authority citation for Part 2570 continues to read as follows:

Authority: 29 U.S.C. 1021, 1108, 1132, 1135, 5 U.S.C. 8477; Reorganization Plan No. 4 of 1978; Secretary of Labor's Order 1–87.

Subpart G is also issued under sec. 306(b)(2) of Pub.L. 107–204, 116 Stat. 745.

7. Revise § 2570.61(c) to read as follows:

§ 2570.61 Definitions.

* * * * *

(c) *Answer* means a written statement that is supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to § 2560.502c–2(g) of this chapter.

* * * * *

8. Revise § 2570.64 to read as follows:

§ 2570.64 Consequences of default.

For 502(c)(2) civil penalty proceedings, this section shall apply in lieu of § 18.5(a) and (b) of this title. Failure of the respondent to file an answer to the notice of determination described in § 2560.502c–2(g) of this chapter within the 30 day period provided by § 2560.502c–2(h) of this chapter shall be deemed to constitute a waiver of his or her right to appear and contest the allegations of the notice of determination, and such failure shall be deemed to be an admission of the facts as alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(2) of the Act. Such notice shall then become the final order of the Secretary, within the meaning of § 2570.61(g) of this subpart, forty-five (45) days from the date of service of the notice.

9. Revise § 2570.94 to read as follows:

§ 2570.94 Consequences of default.

For 502(c)(5) civil penalty proceedings, this section shall apply in lieu of § 18.5(a) and (b) of this title. Failure of the respondent to file an answer to the notice of determination described in § 2560.502c–5(g) of this chapter within the 30 day period provided by § 2560.502c–5(h) of this chapter shall be deemed to constitute a waiver of his or her right to appear and contest the allegations of the notice of determination, and such failure shall be deemed to be an admission of the facts as alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(5) of the Act. Such notice shall then become a final order of the Secretary, within the meaning of § 2570.91(g) of this subpart, forty-five (45) days from the date of the service of the notice.

10. Revise § 2570.114 to read as follows:

§ 2570.114 Consequences of default.

For 502(c)(6) civil penalty proceedings, this section shall apply in lieu of § 18.5(a) and (b) of this title. Failure of the respondent to file an answer to the notice of determination described in § 2560.502c–6(g) of this chapter within the 30 day period provided by § 2560.502c–6(h) of this chapter shall be deemed to constitute a waiver of his or her right to appear and contest the allegations of the notice of determination, and such failure shall be deemed to be an admission of the facts as alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(6) of the Act. Such notice shall then become the final order of the Secretary, within the meaning of § 2570.111(g) of this subpart, forty-five (45) days from the date of service of the notice.

11. Revise Subpart G to Part 2570 to read as follows:

Subpart G—Procedures for the Assessment of Civil Penalties under ERISA Section 502(c)(7)

Sec.
2570.130 Scope of rules.
2570.131 Definitions.
2570.132 Service: Copies of documents and pleadings.
2570.133 Parties, how designated.
2570.134 Consequences of default.
2570.135 Consent order or settlement.
2570.136 Scope of discovery.
2570.137 Summary decision.
2570.138 Decision of the administrative law judge.
2570.139 Review by the Secretary.
2570.140 Scope of review.
2570.141 Procedures for review by the Secretary.

Subpart G—Procedures for the Assessment of Civil Penalties Under ERISA Section 502(c)(7)

§ 2570.130 Scope of rules.

The rules of practice set forth in this subpart are applicable to ''502(c)(7) civil penalty proceedings'' (as defined in § 2570.131(n) of this subpart) under section 502(c)(7) of the Employee Retirement Income Security Act of 1974, as amended (the Act). The rules of procedure for administrative hearings published by the Department's Office of Administrative Law Judges at Part 18 of this title will apply to matters arising under ERISA section 502(c)(7) except as modified by this subpart. These proceedings shall be conducted as expeditiously as possible, and the parties shall make every effort to avoid delay at each stage of the proceedings.

§ 2570.131 Definitions.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of the definitions in § 18.2 of this title:

(a) *Adjudicatory proceeding* means a judicial-type proceeding before an administrative law judge leading to the formulation of a final order;

(b) *Administrative law judge* means an administrative law judge appointed pursuant to the provisions of 5 U.S.C. 3105;

(c) *Answer* means a written statement that is supported by reference to specific circumstances or facts surrounding the notice of determination issued pursuant to § 2560.502c–7(g) of this chapter;

(d) *Commencement of proceeding* is the filing of an answer by the respondent;

(e) *Consent agreement* means any written document containing a specified proposed remedy or other relief acceptable to the Department and consenting parties;

(f) *ERISA* means the Employee Retirement Income Security Act of 1974, as amended;

(g) *Final order* means the final decision or action of the Department of Labor concerning the assessment of a civil penalty under ERISA section 502(c)(7) against a particular party. Such final order may result from a decision of an administrative law judge or the Secretary, the failure of a party to file a statement of reasonable cause described in § 2560.502c–7(e) of this chapter within the prescribed time limits, or the failure of a party to invoke the procedures for hearings or appeals under this title within the prescribed time limits. Such a final order shall constitute final agency action within the meaning of 5 U.S.C. 704;

(h) *Hearing* means that part of a proceeding which involves the submission of evidence, by either oral presentation or written submission, to the administrative law judge;

(i) *Order* means the whole or any part of a final procedural or substantive disposition of a matter under ERISA section 502(c)(7);

(j) *Party* includes a person or agency named or admitted as a party to a proceeding;

(k) *Person* includes an individual, partnership, corporation, employee benefit plan, association, exchange or other entity or organization;

(l) *Petition* means a written request, made by a person or party, for some affirmative action;

(m) *Pleading* means the notice as defined in § 2560.502c–7(g) of this chapter, the answer to the notice, any supplement or amendment thereto, and any reply that may be permitted to any answer, supplement or amendment;

(n) *502(c)(7) civil penalty proceeding* means an adjudicatory proceeding relating to the assessment of a civil penalty provided for in section 502(c)(7) of ERISA;

(o) *Respondent* means the party against whom the Department is seeking to assess a civil sanction under ERISA section 502(c)(7);

(p) *Secretary* means the Secretary of Labor and includes, pursuant to any delegation of authority by the Secretary, any assistant secretary (including the Assistant Secretary for Pension and Welfare Benefits), administrator, commissioner, appellate body, board, or other official; and

(q) *Solicitor* means the Solicitor of Labor or his or her delegate.

§ 2570.132 Service: Copies of documents and pleadings.

For 502(c)(7) penalty proceedings, this section shall apply in lieu of § 18.3 of this title.

(a) *General.* Copies of all documents shall be served on all parties of record. All documents should clearly designate the docket number, if any, and short title of all matters. All documents to be filed shall be delivered or mailed to the Chief Docket Clerk, Office of Administrative Law Judges, 800 K Street, NW., Suite 400, Washington, DC 20001–8002, or to the OALJ Regional Office to which the proceeding may have been transferred for hearing. Each document filed shall be clear and legible.

(b) *By parties.* All motions, petitions, pleadings, briefs, or other documents shall be filed with the Office of Administrative Law Judges with a copy, including any attachments, to all other parties of record. When a party is represented by an attorney, service shall be made upon the attorney. Service of any document upon any party may be made by personal delivery or by mailing a copy to the last known address. The Department shall be served by delivery to the Associate Solicitor, Plan Benefits Security Division, ERISA section 502(c)(7) Proceeding, P.O. Box 1914, Washington, DC 20013. The person serving the document shall certify to the manner and date of service.

(c) *By the Office of Administrative Law Judges.* Service of orders, decisions and all other documents shall be made by regular mail to the last known address.

(d) *Form of pleadings.* (1) Every pleading shall contain information indicating the name of the Pension and

Welfare Benefits Administration (PWBA) as the agency under which the proceeding is instituted, the title of the proceeding, the docket number (if any) assigned by the Office of Administrative Law Judges and a designation of the type of pleading or paper (*e.g.*, notice, motion to dismiss, etc.). The pleading or paper shall be signed and shall contain the address and telephone number of the party or person representing the party. Although there are no formal specifications for documents, they should be typewritten when possible on standard size 8½ x 11 inch paper.

(2) Illegible documents, whether handwritten, typewritten, photocopied, or otherwise, will not be accepted. Papers may be reproduced by any duplicating process provided all copies are clear and legible.

§ 2570.133 Parties, how designated.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of § 18.10 of this title.

(a) The term ''party'' wherever used in this subpart shall include any natural person, corporation, employee benefit plan, association, firm, partnership, trustee, receiver, agency, public or private organization, or government agency. A party against whom a civil penalty is sought shall be designated as ''respondent.'' The Department shall be designated as the ''complainant.''

(b) Other persons or organizations shall be permitted to participate as parties only if the administrative law judge finds that the final decision could directly and adversely affect them or the class they represent, that they may contribute materially to the disposition of the proceedings and their interest is not adequately represented by existing parties, and that in the discretion of the administrative law judge the participation of such persons or organizations would be appropriate.

(c) A person or organization not named as a respondent wishing to participate as a party under this section shall submit a petition to the administrative law judge within fifteen (15) days after the person or organization has knowledge of or should have known about the proceeding. The petition shall be filed with the administrative law judge and served on each person who or organization that has been made a party at the time of filing. Such petition shall concisely state:

(1) Petitioner's interest in the proceeding;

(2) How his or her participation as a party will contribute materially to the disposition of the proceeding;

(3) Who will appear for petitioner;

(4) The issues on which petitioner wishes to participate; and

(5) Whether petitioner intends to present witnesses.

(d) Objections to the petition may be filed by a party within fifteen (15) days of the filing of the petition. If objections to the petition are filed, the administrative law judge shall then determine whether petitioner has the requisite interest to be a party in the proceedings, as defined in paragraph (b) of this section, and shall permit or deny participation accordingly. Where petitions to participate as parties are made by individuals or groups with common interests, the administrative law judge may request all such petitioners to designate a single representative, or he or she may recognize one or more of such petitioners. The administrative law judge shall give each such petitioner, as well as the parties, written notice of the decision on his or her petition. For each petition granted, the administrative law judge shall provide a brief statement of the basis of the decision. If the petition is denied, he or she shall briefly state the grounds for denial and shall then treat the petition as a request for participation as *amicus curiae.*

§ 2570.134 Consequences of default.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of § 18.5(a) and (b) of this title. Failure of the respondent to file an answer to the notice of determination described in § 2560.502c–7(g) of this chapter within the 30 day period provided by § 2560.502c–7(h) of this chapter shall be deemed to constitute a waiver of his or her right to appear and contest the allegations of the notice of determination, and such failure shall be deemed to be an admission of the facts as alleged in the notice for purposes of any proceeding involving the assessment of a civil penalty under section 502(c)(7) of the Act. Such notice shall then become the final order of the Secretary, within the meaning of § 2570.131(g) of this subpart, forty-five (45) days from the date of service of the notice.

§ 2570.135 Consent order or settlement.

For 502(c)(7) civil penalty proceedings, the following shall apply in lieu of § 18.9 of this title.

(a) *General.* At any time after the commencement of a proceeding, but at least five (5) days prior to the date set for hearing, the parties jointly may move to defer the hearing for a reasonable time to permit negotiation of a settlement or an agreement containing findings and an order disposing of the whole or any part of the proceeding. The allowance of such a deferral and the duration thereof shall be in the discretion of the administrative law judge, after consideration of such factors as the nature of the proceeding, the requirements of the public interest, the representations of the parties, and the probability of reaching an agreement which will result in a just disposition of the issues involved.

(b) *Content.* Any agreement containing consent findings and an order disposing of a proceeding or any part thereof shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the notice and the agreement;

(3) A waiver of any further procedural steps before the administrative law judge;

(4) A waiver of any right to challenge or contest the validity of the order and decision entered into in accordance with the agreement; and

(5) That the order and decision of the administrative law judge shall be final agency action.

(c) *Submission.* On or before the expiration of the time granted for negotiations, but, in any case, at least five (5) days prior to the date set for hearing, the parties or their authorized representative or their counsel may:

(1) Submit the proposed agreement containing consent findings and an order to the administrative law judge; or

(2) Notify the administrative law judge that the parties have reached a full settlement and have agreed to dismissal of the action subject to compliance with the terms of the settlement; or

(3) Inform the administrative law judge that agreement cannot be reached.

(d) *Disposition.* In the event a settlement agreement containing consent findings and an order is submitted within the time allowed therefor, the administrative law judge shall issue a decision incorporating such findings and agreement within 30 days of his receipt of such document. The decision of the administrative law judge shall incorporate all of the findings, terms, and conditions of the settlement agreement and consent order of the parties. Such decision shall become final agency action within the meaning of 5 U.S.C. 704.

(e) *Settlement without consent of all parties.* In cases in which some, but not all, of the parties to a proceeding submit a consent agreement to the administrative law judge, the following procedure shall apply:

(1) If all of the parties have not consented to the proposed settlement submitted to the administrative law judge, then such non-consenting parties must receive notice, and a copy, of the proposed settlement at the time it is submitted to the administrative law judge;

(2) Any non-consenting party shall have fifteen (15) days to file any objections to the proposed settlement with the administrative law judge and all other parties;

(3) If any party submits an objection to the proposed settlement, the administrative law judge shall decide within 30 days after receipt of such objections whether he shall sign or reject the proposed settlement. Where the record lacks substantial evidence upon which to base a decision or there is a genuine issue of material fact, then the administrative law judge may establish procedures for the purpose of receiving additional evidence upon which a decision on the contested issues may reasonably be based;

(4) If there are no objections to the proposed settlement, or if the administrative law judge decides to sign the proposed settlement after reviewing any such objections, the administrative law judge shall incorporate the consent agreement into a decision meeting the requirements of paragraph (d) of this section.

§ 2570.136 Scope of discovery.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of § 18.14 of this title.

(a) A party may file a motion to conduct discovery with the administrative law judge. The motion for discovery shall be granted by the administrative law judge only upon a showing of good cause. In order to establish ''good cause'' for the purposes of this section, a party must show that the discovery requested relates to a genuine issue as to a material fact that is relevant to the proceeding. The order of the administrative law judge shall expressly limit the scope and terms of discovery to that for which ''good cause'' has been shown, as provided in this paragraph.

(b) A party may obtain discovery of documents and tangible things otherwise discoverable under paragraph (a) of this section and prepared in anticipation of or for the hearing by or for another party's representative (including his or her attorney, consultant, surety, indemnitor, insurer, or agent) only upon showing that the party seeking discovery has substantial need of the materials or information in the preparation of his or her case and that he or she is unable without undue hardship to obtain the substantial equivalent of the materials or information by other means. In ordering discovery of such materials when the required showing has been made, the administrative law judge shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representatives of a party concerning the proceeding.

§ 2570.137 Summary decision.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of § 18.41 of this title.

(a) *No genuine issue of material fact.* (1) Where no issue of a material fact is found to have been raised, the administrative law judge may issue a decision which, in the absence of an appeal pursuant to §§ 2570.139 through 2570.141 of this subpart, shall become a final order.

(2) A decision made under paragraph (a) of this section shall include a statement of:

(i) Findings of fact and conclusions of law, and the reasons therefor, on all issues presented; and

(ii) Any terms and conditions of the rule or order.

(3) A copy of any decision under this paragraph shall be served on each party.

(b) *Hearings on issues of fact.* Where a genuine question of a material fact is raised, the administrative law judge shall, and in any other case may, set the case for an evidentiary hearing.

§ 2570.138 Decision of the administrative law judge.

For 502(c)(7) civil penalty proceedings, this section shall apply in lieu of § 18.57 of this title.

(a) *Proposed findings of fact, conclusions, and order.* Within twenty (20) days of the filing of the transcript of the testimony, or such additional time as the administrative law judge may allow, each party may file with the administrative law judge, subject to the judge's discretion, proposed findings of fact, conclusions of law, and order together with a supporting brief expressing the reasons for such proposals. Such proposals and briefs shall be served on all parties, and shall refer to all portions of the record and to all authorities relied upon in support of each proposal.

(b) *Decision of the administrative law judge.* Within a reasonable time after the time allowed for the filing of the proposed findings of fact, conclusions of law, and order, or within thirty (30) days after receipt of an agreement containing consent findings and order disposing of the disputed matter in whole, the administrative law judge shall make his or her decision. The decision of the administrative law judge shall include findings of fact and conclusions of law with reasons therefor upon each material issue of fact or law presented on the record. The decision of the administrative law judge shall be based upon the whole record. In a contested case in which the Department and the Respondent have presented their positions to the administrative law judge pursuant to the procedures for 502(c)(7) civil penalty proceedings as set forth in this subpart, the penalty (if any) which may be included in the decision of the administrative law judge shall be limited to the penalty expressly provided for in section 502(c)(7) of ERISA. It shall be supported by reliable and probative evidence. The decision of the administrative law judge shall become final agency action within the meaning of 5 U.S.C. 704 unless an appeal is made pursuant to the procedures set forth in §§ 2570.139 through 2570.141 of this subpart.

§ 2570.139 Review by the Secretary.

(a) The Secretary may review a decision of an administrative law judge. Such a review may occur only when a party files a notice of appeal from a decision of an administrative law judge within twenty (20) days of the issuance of such decision. In all other cases, the decision of the administrative law judge shall become final agency action within the meaning of 5 U.S.C. 704.

(b) A notice of appeal to the Secretary shall state with specificity the issue(s) in the decision of the administrative law judge on which the party is seeking review. Such notice of appeal must be served on all parties of record.

(c) Upon receipt of a notice of appeal, the Secretary shall request the Chief Administrative Law Judge to submit to him or her a copy of the entire record before the administrative law judge.

§ 2570.140 Scope of review.

The review of the Secretary shall not be a de novo proceeding but rather a review of the record established before the administrative law judge. There shall be no opportunity for oral argument.

§ 2570.141 Procedures for review by the Secretary.

(a) Upon receipt of the notice of appeal, the Secretary shall establish a briefing schedule which shall be served on all parties of record. Upon motion of one or more of the parties, the Secretary may, in his or her discretion, permit the submission of reply briefs.

(b) The Secretary shall issue a decision as promptly as possible after receipt of the briefs of the parties. The Secretary may affirm, modify, or set aside, in whole or in part, the decision on appeal and shall issue a statement of reasons and bases for the action(s) taken. Such decision by the Secretary shall be final agency action within the meaning of 5 U.S.C. 704.

Signed at Washington, DC this 16th day of January, 2003.

Ann L. Combs,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 03–1431 Filed 1–23–03; 8:45 am]

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Federal Register

Friday,
January 24, 2003

Part V

Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 46, 47 et al.

Department of Justice

Bureau of Alcohol, Tobacco and Firearms, and Explosives

27 CFR Parts 447, 478 et al.

Reorganization of Title 27, Code of Federal Regulations; Final Rule

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 46, 47, 55, 178, and 179

[T.D. ATF—487]

RIN: 1512–AD06

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Parts 447, 478, 479, 555, and 646

[OLC No. 01–03]

Reorganization of Title 27, Code of Federal Regulations

AGENCIES: Department of the Treasury; Department of Justice.

ACTION: Final rule.

SUMMARY: The Homeland Security Act of 2002 divides the Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury, into two separate agencies, the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) in the Department of Justice, and the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury. These changes require reorganization of title 27 of the Code of Federal Regulations. This final rule renames chapter I, establishes a new chapter II in 27 CFR, and removes certain regulations from chapter I and recodifies them in the new chapter II.

DATES: This rule is effective on January 24, 2003.

FOR FURTHER INFORMATION CONTACT: Lisa M. Gesser, Regulations Division, Alcohol and Tobacco Tax and Trade Bureau, 650 Massachusetts Avenue NW., Washington, DC 20226; 202–927–9347.

SUPPLEMENTARY INFORMATION:

Background

On November 25, 2002, the President signed into law the Homeland Security Act of 2002, Pub. L. No. 107–296, 116 Stat. 2135 (2002). Under title XI, subtitle B, section 1111 of the Act, the ''authorities, functions, personnel, and assets'' of the Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury (the Bureau), are transferred to the Department of Justice, with the exception of certain enumerated authorities that are retained by the Department of the Treasury. The authorities retained by the Secretary of the Treasury include the administration and enforcement of chapters 51 and 52 of the Internal Revenue Code, sections 4181 and 4182 of the Internal Revenue Code, and title 27 of the United States Code.

Section 1111 of the Homeland Security Act further provides that the Bureau will retain its identity as a distinct entity within the Department of Justice known as the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF). The functions retained by the Department of the Treasury are the responsibility of a new Alcohol and Tobacco Tax and Trade Bureau (TTB). The split of the Bureau's functions takes effect on January 24, 2003.

Reorganization of Title 27 CFR

Title 27, Code of Federal Regulations (27 CFR), currently contains one chapter titled ''Chapter I—Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.'' Since the Act divides the Bureau into two separate bureaus, this final rule reorganizes 27 CFR into two chapters, one for each new agency. The current chapter I will be retitled ''Chapter I—Alcohol and Tobacco Tax and Trade Bureau, Department of the Treasury.'' Chapter I will retain all current alcohol and tobacco regulations (except those relating to contraband cigarettes), as well as those related to the Federal firearms and ammunition excise tax. The newly established chapter II will be titled ''Chapter II—Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.'' Chapter II will initially contain the four existing 27 CFR parts concerning firearms and explosives that are being moved from chapter I and recodified in the new chapter. Chapter II will also contain the existing regulations concerning contraband cigarettes.

This final rule does not make any changes to the current requirements of the regulations in 27 CFR. It merely divides the Bureau's current regulations between the new TTB and ATF. In the near future, TTB and the Department of Justice will individually make the necessary technical corrections to their regulations required by the division of the Bureau into the two new bureaus. This may include changes to agency names and addresses, agency acronyms, Web site addresses, delegation order numbers, position titles, and cross references within the regulations.

As noted, this final rule removes four existing parts and one existing subpart in 27 CFR concerning firearms, ammunition, explosives, and contraband cigarettes from chapter I and recodifies them in the new chapter II. These are:

- Part 46, Subpart F—Distribution of Cigarettes, which becomes part 646;
- Part 47, Importation of Arms, Ammunition and Implements of War, which becomes part 447;
- Part 55, Commerce in Explosives, which becomes part 555;
- Part 178, Commerce in Firearms and Ammunition, which becomes part 478; and
- Part 179, Machine Guns, Destructive Devices, and Certain Other Firearms, which becomes part 479.

The following are derivation tables for each of these recodified parts:

DERIVATION TABLE FOR PART 447

The requirements of section:	Are derived from section:
Subpart A	
447.1	47.1
447.2	47.2
Subpart B	
447.11	47.11
Subpart C	
447.21	47.21
447.22	47.22
Subpart D	
447.31	47.31
447.32	47.32
447.33	47.33
447.34	47.34
447.35	47.35
Subpart E	
447.41	47.41
447.42	47.42
447.43	47.43
447.44	47.44
447.45	47.45
447.46	47.46
Subpart F	
447.51	47.51
447.52	47.52
447.53	47.53
447.54	47.54
447.55	47.55
447.56	47.56
447.57	47.57
447.58	47.58
Subpart G	
447.61	47.61
447.62	47.62
447.63	47.63

DERIVATION TABLE FOR PART 478

The requirements of section:	Are derived from section:
Subpart A	
478.1	178.1
478.2	178.2
Subpart B	
478.11	178.11
Subpart C	
478.21	178.21
478.22	178.22
478.23	178.23
478.24	178.24
478.25	178.25
478.25a	178.25a
478.26	178.26
478.27	178.27
478.28	178.28
478.29	178.29
478.29a	178.29a
478.30	178.30
478.31	178.31
478.32	178.32
478.33	178.33
478.33a	178.33a
478.34	178.34
478.35	178.35
478.36	178.36
478.37	178.37
478.38	178.38
478.39	178.39
478.39a	178.39a
478.40	178.40
478.40a	178.40a
Subpart D	
478.41	178.41
478.42	178.42
478.43	178.43
478.44	178.44
478.45	178.45
478.46	178.46
478.47	178.47
478.48	178.48
478.49	178.49
478.50	178.50
478.51	178.51
478.52	178.52
478.53	178.53
478.54	178.54
478.55	178.55
478.56	178.56
478.57	178.57
478.58	178.58
478.59	178.59
478.60	178.60
Subpart E	
478.71	178.71
478.72	178.72
478.73	178.73
478.74	178.74
478.75	178.75
478.76	178.76
478.77	178.77
178.78	178.78

DERIVATION TABLE FOR PART 478—Continued

The requirements of section:	Are derived from section:
Subpart F	
478.91	178.91
478.92	178.92
478.93	178.93
478.94	178.94
478.95	178.95
478.96	178.96
478.97	178.97
478.98	178.98
478.99	178.99
478.100	178.100
478.101	178.101
478.102	178.102
478.103	178.103
Subpart G	
478.111	178.111
478.112	178.112
478.113	178.113
478.113a	178.113a
478.114	178.114
478.115	178.115
478.116	178.116
478.117	178.117
478.118	178.118
478.119	178.119
478.120	178.120
Subpart H	
478.121	178.121
478.122	178.122
478.123	178.123
478.124	178.124
478.124a	178.124a
478.125	178.125
478.125a	178.125a
478.126	178.126
478.126a	178.126a
478.127	178.127
478.128	178.128
478.129	178.129
478.131	178.131
478.132	178.132
478.133	178.133
478.134	178.134
Subpart I	
478.141	178.141
478.142	178.142
478.143	178.143
478.144	178.144
478.145	178.145
478.146	178.146
478.147	178.147
478.148	178.148
478.149	178.149
478.150	178.150
478.151	178.151
478.152	178.152
478.153	178.153
Subpart J [Reserved]	
Subpart K	
478.171	178.171

DERIVATION TABLE FOR PART 479

The requirements of section:	Are derived from section:
Subpart A	
479.1	179.1
Subpart B	
479.11	179.11
Subpart C	
479.21	179.21
479.22	179.22
479.23	179.23
479.24	179.24
479.25	179.25
479.26	179.26
Subpart D	
479.31	179.31
479.32	179.32
479.32a	179.32a
479.33	179.33
479.34	179.34
479.35	179.35
479.36	179.36
479.37	179.37
479.38	179.38
479.39	179.39
479.40	179.40
479.41	179.41
479.42	179.42
479.43	179.43
479.44	179.44
479.45	179.45
479.46	179.46
479.47	179.47
479.48	179.48
479.49	179.49
479.50	179.50
479.51	179.51
479.52	179.52
Subpart E	
479.61	179.61
479.62	179.62
479.63	179.63
479.64	179.64
479.65	179.65
479.66	179.66
479.67	179.67
479.68	179.68
479.69	179.69
479.70	179.70
479.71	179.71
Subpart F	
479.81	179.81
479.82	179.82
479.83	179.83
479.84	179.84
479.85	179.85
479.86	179.86
479.87	179.87
479.88	179.88
479.89	179.89
479.90	179.90
479.91	179.91
479.92	179.92

DERIVATION TABLE FOR PART 479—Continued

The requirements of section:	Are derived from section:
479.93	179.93
Subpart G	
479.101	179.101
479.102	179.102
479.103	179.103
479.104	179.104
479.105	179.105
Subpart H	
479.111	179.111
479.112	179.112
479.113	179.113
479.114	179.114
479.115	179.115
479.116	179.116
479.117	179.117
479.118	179.118
479.119	179.119
479.120	179.120
479.121	179.121
479.122	179.122
Subpart I	
479.131	179.131
Subpart J	
479.141	179.141
479.142	179.142
Subpart K	
479.151	179.151
479.152	179.152
Subpart L	
479.161	179.161
479.162	179.162
479.163	179.163
Subpart M	
479.171	179.171
479.172	179.172
Subpart N	
479.181	179.181
479.182	179.182
Subpart O	
479.191	179.191
479.192	179.192
479.193	179.193

DERIVATION TABLE FOR PART 555

The requirements of section:	Are derived from section:
Subpart A	
555.1	55.1

DERIVATION TABLE FOR PART 555—Continued

The requirements of section:	Are derived from section:
555.2	55.2
Subpart B	
555.11	55.11
Subpart C	
555.21	55.21
555.22	55.22
555.23	55.23
555.24	55.24
555.25	55.25
555.26	55.26
555.27	55.27
555.28	55.28
555.29	55.29
555.30	55.30
555.31	55.31
555.32	55.32
Subpart D	
555.41	55.41
555.42	55.42
555.43	55.43
555.44	55.44
555.45	55.45
555.46	55.46
555.47	55.47
555.48	55.48
555.49	55.49
555.50	55.50
555.51	55.51
555.52	55.52
555.53	55.53
555.54	55.54
555.55	55.55
555.56	55.56
555.57	55.57
555.58	55.58
555.59	55.59
555.60	55.60
555.61	55.61
555.62	55.62
555.63	55.63
Subpart E	
555.71	55.71
555.72	55.72
555.73	55.73
555.74	55.74
555.75	55.75
555.76	55.76
555.77	55.77
555.78	55.78
555.79	55.79
555.80	55.80
555.81	55.81
555.82	55.82
555.83	55.83
Subpart F	
555.101	55.101
555.102	55.102
555.103	55.103
555.104	55.104
555.105	55.105
555.106	55.106

DERIVATION TABLE FOR PART 555—Continued

The requirements of section:	Are derived from section:
555.107	55.107
555.108	55.108
555.109	55.109
Subpart G	
555.121	55.121
555.122	55.122
555.123	55.123
555.124	55.124
555.125	55.125
555.126	55.126
555.127	55.127
555.128	55.128
555.129	55.129
555.130	55.130
Subpart H	
555.141	55.141
555.142	55.142
Subpart I	
555.161	55.161
555.162	55.162
555.163	55.163
555.164	55.164
555.165	55.165
555.166	55.166
Subpart J	
555.180	55.180
555.181	55.181
555.182	55.182
555.183	55.183
555.184	55.184
555.185	55.185
555.186	55.186
Subpart K	
555.201	55.201
555.202	55.202
555.203	55.203
555.204	55.204
555.205	55.205
555.206	55.206
555.207	55.207
555.208	55.208
555.209	55.209
555.210	55.210
555.211	55.211
555.212	55.212
555.213	55.213
555.214	55.214
555.215	55.215
555.216	55.216
555.217	55.217
555.218	55.218
555.219	55.219
555.220	55.220
555.221	55.221
555.222	55.222
555.223	55.223
555.224	55.224

DERIVATION TABLE FOR PART 646

The requirements of section:	Are derived from section:
646.141	46.141
646.142	46.142
646.143	46.143
646.146	46.146
646.147	46.147
646.150	46.150
646.153	46.153
646.154	46.154
646.155	46.155

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule under the Administrative Procedure Act (5 U.S.C. 553), the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

This final rule is not a significant regulatory action as defined in Executive Order 12866. Accordingly, this final rule is not subject to the analysis this Executive Order requires.

Administrative Procedure Act

Because this final rule merely makes technical amendments to improve the organization of the regulations, no notice of proposed rulemaking and public comment period is required under 5 U.S.C. 553(b)(B). Similarly, because this final rule makes no substantive changes and is merely a recodification of existing regulations, this final rule is not subject to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Lisa M. Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 46

Administrative practice and procedure, Authority delegations, Cigars and cigarettes, Claims, Excise taxes, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Surety bonds, Tobacco.

27 CFR Part 47

Administrative practice and procedure, Arms control, Arms and munitions, Authority delegation, Chemicals, Customs duties and inspection, Imports, Penalties, Reporting and recordkeeping requirements, Scientific equipment, Seizures and forfeitures.

27 CFR Part 55

Administrative practice and procedure, Authority delegations, Customs duties and inspection, Explosives, Hazardous materials, Imports, Penalties, Reporting and recordkeeping requirements, Safety, Security measures, Seizures and forfeitures, Transportation, Warehouses.

27 CFR Part 178

Administrative practice and procedure, Arms and munitions, Authority delegations, Customs duties and inspection, Domestic violence, Exports, Imports, Law enforcement personnel, Military personnel, Nonimmigrant aliens, Penalties, Reporting requirements, Research, Seizures and forfeitures, Transportation.

27 CFR Part 179

Administrative practice and procedure, Arms and munitions, Authority delegations, Customs duties and inspection, Exports, Imports, Military personnel, Penalties, Reporting requirements, Research, Seizures and forfeitures, Transportation.

27 CFR Part 447

Administrative practice and procedure, Arms control, Arms and munitions, Authority delegation, Chemicals, Customs duties and inspection, Imports, Penalties, Reporting and recordkeeping requirements, Scientific equipment, Seizures and forfeitures.

27 CFR Part 478

Administrative practice and procedure, Arms and munitions, Authority delegations, Customs duties and inspection, Domestic violence, Exports, Imports, Law enforcement personnel, Military personnel, Nonimmigrant aliens, Penalties, Reporting requirements, Research, Seizures and forfeitures, Transportation.

27 CFR Part 479

Administrative practice and procedure, Arms and munitions, Authority delegations, Customs duties and inspection, Exports, Imports, Military personnel, Penalties, Reporting requirements, Research, Seizures and forfeitures, Transportation.

27 CFR Part 555

Administrative practice and procedure, Authority delegations, Customs duties and inspection, Explosives, Hazardous materials, Imports, Penalties, Reporting and recordkeeping requirements, Safety, Security measures, Seizures and forfeitures, Transportation, Warehouses.

27 CFR Part 646

Administrative practice and procedure, Authority delegations, Cigars and cigarettes, Claims, Excise taxes, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Surety bonds, Tobacco.

Authority and Issuance

For the reasons discussed in the preamble, the Department of the Treasury and the Department of Justice amend title 27 of the Code of Federal Regulations as follows:

TITLE 27—ALCOHOL, TOBACCO PRODUCTS AND FIREARMS

CHAPTER I—ALCOHOL AND TOBACCO TAX AND TRADE BUREAU, DEPARTMENT OF THE TREASURY

1. Revise the title of 27 CFR chapter I to read as set forth above.

CHAPTER II—BUREAU OF ALCOHOL, TOBACCO, FIREARMS, AND EXPLOSIVES, DEPARTMENT OF JUSTICE

Subchapter A [Reserved]

Subchapter B—Firearms and Ammunition

Subchapter C—Explosives

Subchapter D—Miscellaneous Regulations Relating To Alcohol and Tobacco

2. Amend title 27 CFR by establishing chapter II and its related subchapters to read as set forth above.

Chapter I, Subchapter C

PART 47—[REDESIGNATED AS PART 447]

3. Transfer 27 CFR part 47 from chapter I, subchapter C, to chapter II, subchapter B and redesignate as 27 CFR part 447.

Chapter II, Subchapter B

PART 447—IMPORTATION OF ARMS, AMMUNITION AND IMPLEMENTS OF WAR

4. The authority citation for the newly redesignated 27 CFR part 447 continues to read as follows:

Authority: 22 U.S.C. 2778.

5. Amend the newly redesignated part 447 as follows:

AMENDMENT TABLE FOR PART 447

Amend:	By removing the reference to:	And adding in its place:
§ 447.2(a)	§ 47.21	§ 447.21
§ 447.2(a) (two times)	Part 178	Part 478
§ 447.2(a) (two times)	Part 179	Part 479
§ 447.2(b)	Part 178 or 179	Part 478 or 479
§ 447.2(b)	Part 178 or 27 CFR Part 179	Part 478 or 479
§ 447.2(b)	Parts 178 and 179	Parts 478 and 479
§ 447.2(c)	Part 178	Part 478
§ 447.11, definition of ''Appropriate ATF officer''	Part 47	Part 447
§ 447.11, definition of ''Defense articles'' (two times).	§ 47.21 or § 47.22	§ 447.21 or § 447.22
§ 447.11, definition of ''Import list''	§ 47.21	§ 447.21
§ 447.11, definition of ''This chapter'' (two times).	Chapter I	Chapter II
§ 447.34(a)	Parts 178 and 179	Parts 478 and 479
§ 447.34(b)	§ 178.129	§ 478.129
§ 447.34(b)	Part 178	Part 478
§ 447.41(a)	Parts 178 or 179	Parts 478 or 479
§ 447.41(b)	178.115	478.115
§ 447.42(a)(1) (introductory paragraph)	§ 47.41	§ 447.41
§ 447.42(b)	§ 55.183 of this title	§ 555.183 of this chapter
§ 447.52(e) (introductory text)	Part 179	Part 479
§ 447.52(e) (introductory text)	178.118	478.118
§ 447.56(a)	Parts 178 and 179	Parts 478 and 479
§ 447.57(a)(1)	Parts 178 or 179	Parts 478 or 479
§ 447.57(b)(2)	§ 178.118	§ 478.118

Chapter I, Subchapter C

PART 55—[REDESIGNATED AS PART 555]

6. Transfer 27 CFR part 55 from chapter I, subchapter C, to chapter II, subchapter C and redesignate as 27 CFR part 555.

Chapter II, Subchapter C

PART 555—COMMERCE IN EXPLOSIVES

7. The authority citation for the newly redesignated 27 CFR part 555 continues to read as follows:

Authority: 18 U.S.C. 847.

8. Amend the newly redesignated part 555 as follows:

AMENDMENT TABLE FOR PART 555

Amend:	By removing the reference to:	And adding in its place:
§ 555.2	Part 178	Part 478.
§ 555.2	Part 179	Part 479.
§ 555.2	Part 47	Part 447.
§ 555.11, definition of ''Explosive materials''	§ 55.23	§ 555.23.
§ 555.26(a)(1)	§ 55.105(c)	§ 555.105(c).
§ 555.26(d)	§ 55.180	§ 555.180.
§ 555.41(b) (introductory text)	§ 55.42	§ 555.42.
§ 555.41(b) (introductory text)	§ 55.45	§ 555.45
§ 555.41(c)	§ 55.43	§ 555.43.
§ 555.41(c)	§ 55.45	§ 555.45.
§ 555.45(b)	§ 55.41(a)	§ 555.41(a).
§ 555.46(a)	§ 55.45	§ 555.45.
§ 555.46(b)	§ 55.45	§ 555.45.
§ 555.49(b)(6)	§ 55.202	§ 555.202.
§ 555.49(c)	§ 55.83 or § 55.142	§ 555.83 or § 555.142.
§ 555.49(c)	§ 55.142	§ 555.142.
§ 555.52(a)	§ 55.202	§ 555.202.
§ 555.52(a)	§ 55.41(b)	§ 555.41(b).
§ 555.52(b)	§ 55.202	§ 555.202.
§ 555.53	§ 55.59	§ 555.59.
§ 555.55	§ 55.202	§ 555.202.
§ 555.57	§ 55.45	§ 555.45.
§ 555.57	§ 55.42(b) or § 55.43(b)	§ 555.42(b) or § 555.43(b).
§ 555.58	§ 55.45	§ 555.45.
§ 555.61	§ 55.128	§ 555.128.
§ 555.71	§ 55.74	§ 555.74.
§ 555.72	§ 55.49	§ 555.49.

AMENDMENT TABLE FOR PART 555—Continued

Amend:	By removing the reference to:	And adding in its place:
§ 555.73	§ 55.77	§ 555.77.
§ 555.73	§ 55.82	§ 555.82.
§ 555.74 (two times)	§ 55.71	§ 555.71.
§ 555.75	§ 55.77	§ 555.77.
§ 555.76(b) (introductory text)	§ 55.79	§ 555.79.
§ 555.76(b)(3)	§ 55.45	§ 555.45.
§ 555.76(c)	§ 55.81	§ 555.81.
§ 555.77	§ 55.73 or § 55.75	§ 555.73 or § 555.75.
§ 555.78	§§ 55.73 and 55.75	§§ 555.73 and 555.75.
§ 555.79	§ 55.73 or § 55.75	§ 555.73 or § 555.75.
§ 555.79	§ 55.75	§ 555.75.
§ 555.79	§ 55.76(b)	§ 555.76(b).
§ 555.102(b)	§ 55.103	§ 555.103.
§ 555.102(b)	§ 55.105(d)	§ 555.105(d).
§ 555.103(e)	§ 55.51	§ 555.51.
§ 555.104 (introductory text)	§ 55.49(a)	§ 555.49(a).
§ 555.104 (introductory text)	§ 55.103	§ 555.103.
§ 555.105(b) (two times)	§ 55.126	§ 555.126.
§ 555.105(f)	§ 55.103(a)	§ 555.103(a).
§ 555.106(a)	§ 55.105(c)	§ 555.105(c).
§ 555.106(c)(1)	§ 55.142(d) and (e)	§ 555.142(d) and (e).
§ 555.106(d)	§ 55.105(g)	§ 555.105(g).
§ 555.108(a)	§ 55.103	§ 555.103.
§ 555.108(c)	Part 47	Part 447.
§ 555.108(d)	§ 55.183	§ 555.183.
§ 555.121(a)(2)	§ 55.128	§ 555.128.
§ 555.121(b)	§ 55.24	§ 555.24.
§ 555.122(a)(4)	§ 55.127	§ 555.127.
§ 555.122(e)	§ 55.126	§ 555.126.
§ 555.123(a)(4)	§ 55.127	§ 555.127.
§ 555.123(f)	§ 55.126	§ 555.126.
§ 555.124(a)(4)	§ 55.127	§ 555.127.
§ 555.124(f)	§ 55.126	§ 555.126.
§ 555.125(a)(4)	§ 55.127	§ 555.127.
§ 555.125(c)	§ 55.124(c)	§ 555.124(c).
§ 555.125(d)	§ 55.126	§ 555.126.
§ 555.126(b)	§ 55.105(c)	§ 555.105(c).
§ 555.127	§§ 55.122, 55.123, 55.124, and 55.125	§§ 555.122, 555.123, 555.124, and 555.125.
§ 555.127	§ 55.30	§ 555.30.
§ 555.128	§ 55.61	§ 555.61.
§ 555.129	§ 55.180	§ 555.180.
§ 555.141(a) (introductory text)	§§ 55.180 and 55.181	§§ 555.180 and 555.181.
§ 555.165	§ 55.30	§ 555.30.
§ 555.180(d)(4)	§ 55.202(a)	§ 555.202(a).
§ 555.182 (introductory text)	§§ 55.180 and 55.181	§§ 555.180 and 555.181.
§ 555.183(a)	§ 55.180(b)	§ 555.180(b).
§ 555.183(b)	§ 55.182	§ 555.182.
§ 555.201(a)	§ 55.29	§ 555.29.
§ 555.201(c)	§ 55.63	§ 555.63.
§ 555.201(d)	§§ 55.221 through 55.224	§§ 555.221 through 555.224.
§ 555.201(e)	§ 55.202(a)	§ 555.202(a).
§ 555.202(a)	§ 55.201(e)	§ 555.201(e).
§ 555.202(c)	§ 55.11	§ 555.11.
§ 555.203 (introductory text)	§ 55.202	§ 555.202.
§ 555.203(a)	§§ 55.206 and 55.213	§ 555.206 and 555.213.
§ 555.203(b)	§§ 55.206, 55.208(b), and 55.213	§§ 555.206, 555.208(b), and 555.213.
§ 555.203(c)	§§ 55.206 and 55.213	§§ 555.206 and 555.213.
§ 555.203(d)	§§ 55.206(b), 55.210(b), and 55.213	§§ 555.206(b), 555.210(b), and 555.213.
§ 555.203(d)	§§ 55.206(c), 55.211(b), and 55.213	§§ 555.206(c), 555.211(b), and 555.213.
§ 555.203(d)	§§ 55.206(a), 55.210(b), and 55.213	§§ 555.206(a), 555.210(b), and 555.213.
§ 555.203(e)	§§ 55.206(c), 55.211(b), and 55.213	§§ 555.206(c), 555.211(b), and 555.213.
§ 555.205(d)	§ 55.106	§ 555.106.
§ 555.206(a)	§ 55.218	§ 555.218.
§ 555.206(b) (two times)	§ 55.219	§ 555.219.
§ 555.206(b)	§ 55.224	§ 555.224.
§ 555.206(c)(1)	§ 55.218	§ 555.218.
§ 555.206(c)(2)	§ 55.220	§ 555.220.
§ 555.206(c)(2)	§ 55.218	§ 555.218.
§ 555.208(b)(1)	§ 55.213	§ 555.213.
§ 555.211(b)(1)	§ 55.206	§ 555.206.
§ 555.218, Notes to the Table of Distances for Storage of Explosives (paragraph 1).	§ 55.11	§ 555.11.

AMENDMENT TABLE FOR PART 555—Continued

Amend:	By removing the reference to:	And adding in its place:
§ 555.220, Notes of Table of Separation Distances of Ammonium Nitrate and Blasting Agents from Explosives or Blasting Agents (paragraph 2).	§ 55.218	§ 555.218.
§ 555.220, Notes of Table of Separation Distances of Ammonium Nitrate and Blasting Agents from Explosives or Blasting Agents (paragraph 3).	§ 55.218	§ 555.218.
§ 555.220, Notes of Table of Separation Distances of Ammonium Nitrate and Blasting Agents from Explosives or Blasting Agents (paragraph 6).	§ 55.218	§ 555.218.
§ 555.223, table notes (paragraph 3)	§ 55.222	§ 555.222.
§ 555.223, table notes (paragraph 3)	§§ 55.218 and 55.224	§§ 555.218 and 555.224.
§ 555.223, table notes (paragraph 5)	§ 55.222	§ 555.222.
§ 555.224, center column in table	§ 55.218	§ 555.218.
§ 555.224, table notes (paragraph 4)	§ 55.218	§ 555.218.

Chapter I, Subchapter M

PART 178—[REDESIGNATED AS PART 478]

9. Transfer 27 CFR part 178 from chapter I, subchapter M, to chapter II, subchapter B and redesignate as 27 CFR part 478.

Chapter II, Subchapter B

PART 478—COMMERCE IN FIREARMS AND AMMUNITION

10. The authority citation for the newly redesignated 27 CFR part 478 continues to read as follows:

Authority: 5 U.S.C. 552(a); 18 U.S.C. 847, 921–930; 44 U.S.C. 3504(h).

11. Amend the newly redesignated part 478 as follows:

AMENDMENT TABLE FOR PART 478

Amend:	By removing the reference to:	And adding in its place:
Editorial Note	Part 178	This part.
§ 478.2	Part 179	Part 479.
§ 478.2	Part 47	Part 447.
§ 478.11 (Editorial Note:)	§ 178.11	§ 478.11.
§ 478.28(c)	Part 179	Part 479.
§ 478.29(b)	§ 178.96(c)	§ 478.96(c).
§ 478.29(c)	§§ 178.30 and 178.97	§§ 478.30 and 478.97.
§ 478.36(a)	Part 179	Part 479.
§ 478.36(b)	Part 179	Part 479.
§ 478.37(c)	§ 178.149	§ 478.149.
§ 478.39(b)(2)	§ 178.151	§ 478.151.
§ 478.40(b)(9)	§ 178.153	§ 478.153.
§ 478.40(c)(5)	§ 178.132	§ 478.132.
§ 478.40a(b)(5)	§ 178.153	§ 478.153.
§ 478.40a(c)(5)	§ 178.132	§ 478.132.
§ 478.41(b)	§ 178.42	§ 478.42.
§ 478.41(b)	§ 178.44	§ 478.44.
§ 478.41(b)	§ 178.47	§ 478.47.
§ 478.41(b)	§ 178.50	§ 478.50.
§ 478.41(c)	§ 178.42	§ 478.42.
§ 478.41(c)	§ 178.44	§ 478.44.
§ 478.41(c)	§ 178.47	§ 478.47.
§ 478.41(d)	§ 178.93	§ 478.93.
§ 478.45 (two times)	§ 178.44	§ 478.44.
§ 478.47(c)	§ 178.78, § 178.143, or § 178.144	§ 478.78, § 478.143, or § 478.144.
§ 478.47(c)	§ 178.144	§ 478.144.
§ 478.50(c)	§ 178.100	§ 478.100.
§ 478.50(d)	§ 178.100	§ 478.100.
§ 478.51	§ 178.56	§ 478.56.
§ 478.52(a)	§ 178.44	§ 478.44.
§ 478.52(b)	§ 178.71	§ 478.71.
§ 478.54	§ 178.44	§ 478.44.
§ 478.55	§ 178.44	§ 478.44.
§ 478.57(a)	§ 178.127	§ 478.127.
§ 478.57(b)	§ 178.40(b)	§ 478.40(b).
§ 478.57(b)	§§ 178.40(c) and 178.132	§§ 478.40(c) and 478.132.
§ 478.57(c)	§ 178.40a(b)	§ 478.40a(b).
§ 478.57(c)	§§ 178.40a(c) and 178.132	§§ 478.40a(c) and 478.132.

AMENDMENT TABLE FOR PART 478—Continued

Amend:	By removing the reference to:	And adding in its place:
§ 478.71	§ 178.47	§ 478.47.
§ 478.72	§ 178.47	§ 478.47.
§ 478.73(b)	§ 178.74	§ 478.74.
§ 478.92(a)(4)(iii)	§ 178.11	§ 478.11.
§ 478.93	§ 178.50	§ 478.50.
§ 478.93	§ 178.99(c)	§ 478.99(c).
§ 478.93	§ 178.125(a)	§ 478.125(a).
§ 478.95	§ 178.94	§ 478.94.
§ 478.96(b)	§ 178.102(a)	§ 478.102(a).
§ 478.96(b)	§ 178.124	§ 478.124.
§ 478.96(c)(1)(ii)	§ 178.102	§ 478.102.
§ 478.96(c)(1)(iii)	§ 178.124	§ 478.124.
§ 478.97(a)	§ 178.99(b) or § 178.99(c)	§ 478.99(b) or § 478.99(c).
§ 478.97(a)	§ 178.102	§ 478.102.
§ 478.98(b) (two times)	Part 179	Part 479.
§ 478.99(a)	§ 178.96(c)	§ 478.96(c).
§ 478.99(a)	§ 178.97	§ 478.97.
§ 478.99(c)(1)	§ 178.143	§ 478.143.
§ 478.99(c)(1)	§ 178.144	§ 478.144.
§ 478.99(c)(5)	§ 178.32(f)	§ 478.32(f).
§ 478.99(d)(3)	§ 178.149	§ 478.149.
§ 478.99(e)	§ 178.125(c)	§ 478.125(c).
§ 478.100(a)(1)	§ 178.91	§ 478.91.
§ 478.102(a)(3)	§ 178.124(c)	§ 478.124(c).
§ 478.102(b)	§ 178.129	§ 478.129.
§ 478.102(d)(2)	Part 179	Part 479.
§ 478.102(d)(3)	§ 178.150	§ 478.150.
§ 478.102(e)	§ 178.131	§ 478.131.
§ 478.112(a)	§ 178.11	§ 478.11.
§ 478.112(d)(2)	§ 178.92	§ 478.92.
§ 478.113(a)	§ 178.11	§ 478.11.
§ 478.116	§ 178.119(b)	§ 478.119(b).
§ 478.118	Part 47	Part 447.
§ 478.118	Part 179	Part 479.
§ 478.119(c)(7)	§ 178.40a(b)	§ 478.40a(b).
§ 478.119(f)(2)	§ 178.92	§ 478.92.
§ 478.119(g)	§ 178.116	§ 478.116.
§ 478.121(a)	§ 178.129	§ 478.129.
§ 478.121(a)	§ 178.125	§ 478.125.
§ 478.121(b) (two times)	§ 178.23	§ 478.23.
§ 478.121(d)	§ 178.100(c)	§ 478.100(c).
§ 478.122(b)	§ 178.149	§ 478.149.
§ 478.122(d)	§§ 178.124 and 178.125	§§ 478.124 and 478.125.
§ 478.123(b)	§ 178.149	§ 478.149.
§ 478.123(b)	§ 178.122	§ 478.122.
§ 478.123(d)	§§ 178.124 and 178.125	§§ 478.124 and 478.125.
§ 478.124(c)(3)(i)	§ 178.11	§ 478.11.
§ 478.124(c)(3)(ii)	§ 178.11	§ 478.11.
§ 478.124(c)(3)(iv)	§ 178.102	§ 478.102.
§ 478.124(d)	§ 178.96(c)	§ 478.96(c).
§ 478.124(f)	§ 178.102(a)	§ 478.102(a).
§ 478.124a(a) (two times)	§ 178.125	§ 478.125.
§ 478.124a(e) (introductory text)	§ 178.124(c)	§ 478.124(c).
§ 478.124a(e)(2)	§ 178.96(c)	§ 478.96(c).
§ 478.124a(f)	§ 178.124(f)	§ 478.124(f).
§ 478.125(b)	§ 178.122(b)	§ 478.122(b).
§ 478.125(c) (two times)	§ 178.99(e)	§ 478.99(e).
§ 478.125(c)	§ 178.122(b)	§ 478.122(b).
§ 478.125(e)	§ 178.124a	§ 478.124a.
§ 478.125(f)(2)(i)	§ 178.11	§ 478.11.
§ 478.125(f)(2)(ii)	§ 178.11	§ 478.11.
§ 478.125a(a) (introductory text)	§ 178.102	§ 478.102.
§ 478.125a(a)(2)	§ 178.125(e)	§ 478.125(e).
§ 478.125a(a)(3)	§ 178.125(e)	§ 478.125(e).
§ 478.129(b)	§ 178.124(b)	§ 478.124(b).
§ 478.129(c)	§ 178.150(c)	§ 478.150(c).
§ 478.129(f)	§§ 178.40(c) and 178.132	§§ 478.40(c) and 478.132.
§ 478.131(a)(1)	§ 178.102(d)	§ 478.102(d).
§ 478.131(a)(1)	§ 178.102(a)	§ 478.102(a).
§ 478.131(a)(2)	§ 178.102(d)(1)	§ 478.102(d)(1).
§ 478.131(a)(3)	§§ 178.102(d)(3) and 178.150	§§ 478.102(d)(3) and 478.150.
§ 478.131(a)(3)	§ 178.129(c)	§ 478.129(c).

AMENDMENT TABLE FOR PART 478—Continued

Amend:	By removing the reference to:	And adding in its place:
§ 478.132(b)(2)	§ 178.40(b)(7) and 178.40(b)(3)	§§ 478.40(b)(7) and 478.40(b)(3).
§ 478.133	§ 178.40(c)	§ 478.40(c).
§ 478.141 (introductory and text)	§§ 178.32(a)(9) and (d)(9) and 178.99(c)(9)	§§ 478.32(a)(9) and (d)(9) 478.99(c)(9).
§ 478.144(a)	§ 178.32	§ 478.32.
§ 478.144(i)(1)	§ 178.32(a)	§ 478.32(a).
§ 478.145	§ 178.98	§ 478.98.
§ 478.147	§ 178.124(a)	§ 478.124(a).
§ 478.149	§§ 178.37and 178.99(d)	§§ 478.37 and 478.99(d).
§ 478.150(a) (introductory text)	§ 178.102(d)(3)	§ 478.102(d)(3).
§ 478.150(a) (introductory text)	§ 178.102(a)(1)	§ 478.102(a)(1).
§ 478.150(c)	§ 178.129(c)	§ 478.129(c).
§ 478.151(a)	§ 178.39	§ 478.39.
§ 478.153	§ 178.40	§ 478.40.
§ 478.153	§ 178.40a	§ 478.40a.

Chapter I, Subchapter M

PART 179—[REDESIGNATED AS PART 479]

12. Transfer 27 CFR part 179 from chapter I, subchapter M to chapter II, subchapter B and redesignate as 27 CFR part 479.

Chapter II, Subchapter B

PART 479—MACHINE GUNS, DESTRUCTIVE DEVICES, AND CERTAIN OTHER FIREARMS

13. The authority citation for the newly redesignated 27 CFR part 479 continues to read as follows:

Authority: 26 U.S.C. 7805.

14. Amend the newly redesignated part 479 as follows:

AMENDMENT TABLE FOR PART 479

Amend:	By removing the reference to:	And adding in its place:
§ 479.25	§ 179.24	§ 479.24.
§ 479.31(a)	§ 179.32	§ 479.32.
§ 479.31(b)	§§ 179.38–179.39	§§ 479.38–479.39.
§ 479.32(b)	§ 179.32a	§ 479.32a.
§ 479.32a(a)	§ 179.32	§ 479.32.
§ 479.34(b)(3)	§ 179.35	§ 479.35.
§ 479.34(b)(6)	Part 178	Part 478.
§ 479.34(e)	§ 178.44(a)	§ 478.44(a).
§ 479.38	§ 179.46	§ 479.46.
§ 479.42	§ 179.49	§ 479.49.
§ 479.43	§ 179.42	§ 479.42.
§ 479.44	§ 179.42	§ 479.42.
§ 479.44	§ 179.34	§ 479.34.
§ 479.46	§ 179.34	§ 479.34.
§ 479.48	§ 179.34	§ 479.34.
§ 479.49	§ 179.46	§ 479.46.
§ 479.49	§ 179.50	§ 479.50.
§ 479.50	§ 179.51	§ 479.51.
§ 479.52	§ 179.23	§ 479.23.
§ 479.62	§ 179.63	§ 479.63.
§ 479.62	§ 179.67	§ 479.67.
§ 479.69	§ 179.62	§ 479.62.
§ 479.70	§ 179.62	§ 479.62.
§ 479.84	§ 179.85	§ 479.85.
§ 479.87	§ 179.67	§ 479.67.
§ 479.89	§ 179.90	§ 479.90.
§ 479.90(b)	§ 179.85	§ 479.85.
§ 479.91	§ 179.90	§ 479.90.
§ 479.92	§ 178.28	§ 478.28.
§ 479.93	§ 178.98	§ 478.98.
§ 479.111(a)(3)	Part 178	Part 478
§ 479.111(b)	Part 178	Part 478.
§ 479.111(c)	Part 178	Part 478.
§ 479.112(a)	§ 178.112	§ 478.112.
§ 479.118	§ 179.117	§ 479.117.
§ 479.119	§ 178.28	§ 478.28.
§ 479.120	§ 179.118	§ 479.118.
§ 479.120	§ 179.172	§ 479.172.
§ 479.121	§§ 179.114 and 179.115	§§ 479.114 and 479.115.
§ 479.122(a)	Part 47	Part 447.
§ 479.131	Part 178	Part 478.

AMENDMENT TABLE FOR PART 479—Continued

Amend:	By removing the reference to:	And adding in its place:
§ 479.192	Part 178	Part 478.
§ 479.193	Part 47	Part 447.

Chapter I, Subchapter B

PART 46—[AMENDED]

15. Transfer 27 CFR part 46, subpart F (§§ 46.141–46.155), from chapter I, subchapter B, to 27 CFR, chapter II, subchapter D and redesignate as ''Part 646—Contraband Cigarettes''.

Chapter II, Subchapter D

PART 646—CONTRABAND CIGARETTES

16. Add an authority citation for the newly redesignated 27 CFR part 646 to read as follows:

Authority: 18 U.S.C. 2341–2346, unless otherwise noted.

17. Amend the newly redesignated part 646 as follows:

AMENDMENT TABLE FOR PART 646

Amend:	By removing the reference to:	And adding in its place:
§ 646.141 (section heading)	Subpart	Part.
§ 646.142	Subpart	Part.
§ 646.143 (introductory text)	Subpart	Part.
§ 646.146	Subpart	Part.
§ 646.146	§ 46.147	§ 646.147.
§ 646.147(a) (introductory text)	§ 46.143	§ 646.143.
§ 646.147(b)	§ 46.143	§ 646.143.
§ 646.150(a)	§§ 46.146 and 46.147	§§ 646.146 and 646.147.
§ 646.153 (introductory text)	§§ 46.146 through 46.147	§§ 646.146 through 646.147
§ 646.154(b)	Subpart	Part.

Dated: January 14, 2003.

Bradley A. Buckles,

Director, Bureau of Alcohol, Tobacco and Firearms.

Dated: January 15, 2003.

Timothy E. Skud,

Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).

Dated: January 21, 2003.

Joan L. Larsen,

Deputy Assistant Attorney General.

[FR Doc. 03–1657 Filed 1–23–03; 8:45 am]

BILLING CODE 4810–31–P; 4410–19–P

Federal Register

Friday,
January 24, 2003

Part VI

Department of Transportation

Transportation Security Administration

49 CFR Part 1540

Threat Assessments Regarding Citizens of the United States and Alien Holders Who Hold or Apply for FAA Certificates; Final Rules

DEPARTMENT OF TRANSPORTATION

Transportation Security Administration

49 CFR Part 1540

[Docket No. TSA–2002–13732; Amendment No. 1540–3]

RIN 2110–AA14

Threat Assessments Regarding Citizens of the United States Who Hold or Apply for FAA Certificates

AGENCY: Transportation Security Administration (TSA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This final rule establishes the procedure by which TSA will notify the subject individual and the Federal Aviation Administration (FAA) of TSA's assessment that an individual who is a citizen of the United States and holds or is applying for an FAA airman certificate, rating, or authorization poses a security threat. This procedure provides such individuals notice and an opportunity to be heard before TSA makes a final decision, while furthering the federal government's important and immediate interest in protecting national security and providing the nation with a safe and secure transportation system.

DATES: Effective on January 24, 2003. Submit comments by March 25, 2003.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number TSA–2002–13732 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that TSA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov.* You may review the public docket containing comments to these regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Brandon Straus, Office of the Chief Counsel, Transportation Security Administration, 400 Seventh Street, SW., Washington, DC 20590–0001; telephone (202) 493–1224; e-mail: *brandon.straus@tsa.dot.gov.* For information regarding the Economic Analysis, contact Jenny R. Randall, Economist, Office of Security Regulation & Policy, Transportation Security Administration, 400 Seventh Street, SW., Washington, DC 20590–0001; telephone (202) 385–1554; e-mail: jenny.randall@tsa.dot.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

This final rule is being adopted without prior notice and prior public comment. However, the Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 1134; February 26, 1979) provide that, to the maximum extent possible, operating administrations within DOT should provide an opportunity for public comment on regulations issued without prior notice. Accordingly, interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting this amendment. The most helpful comments will reference a specific portion of the rule, explain the reason for any recommended change, and include supporting data. See **ADDRESSES** above for information on how to submit comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with TSA personnel concerning this rulemaking. The docket is available for public inspection before and after the comment closing date.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these rules in light of the comments we receive.

Electronic Access

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(2) Accessing the Government Printing Office's Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html;* or

(3) Visiting the TSA's Law and Policy Web page at *http://www.tsa.dot.gov/public/index.jsp.*

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this rulemaking.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the TSA to comply with small entity requests for information and advice about compliance with statutes and regulations within the TSA's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT.** Persons can obtain further information regarding SBREFA on the Small Business Administration's Web page at *http://www.sba.gov/advo/laws/law_lib.html.*

Background

Following the terrorist attacks on the United States on September 11, 2001, Congress recognized the need for a fundamental change in the federal government's approach to ensuring the security of civil aviation. The September 11 attacks highlighted the fact that the security of the civil aviation system is critical to national security and essential to the basic freedom of Americans to move in intrastate, interstate, and international transportation. *See* H. R. Conf. Rep. 107–296, 107th Cong., 1st Sess. 53 (2001).

In order to address the need for heightened security in civil aviation and other modes of transportation, Congress passed the Aviation and Transportation Security Act (ATSA), Pub. L. 107–71, 115 Stat. 597 (November 19, 2001). ATSA established the TSA within DOT, operating under the direction of the Under Secretary of Transportation for Security (Under Secretary). TSA is responsible for security in all modes of transportation regulated by DOT, including civil aviation. Accordingly, ATSA transferred the responsibility for civil aviation security from the FAA to TSA.

ATSA Requirements

As part of its security mission, TSA is responsible for assessing intelligence and other information in order to identify individuals who pose a threat to transportation security and to coordinate countermeasures with other Federal agencies, including the FAA, to address such threats. *See* 49 U.S.C. 114(f)(1)–(5), (h)(1)–(4). Specifically, Congress required TSA to work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations. 49 U.S.C. 114(f)(13).

In the course of carrying out this responsibility, TSA receives information from other federal agencies and other

sources identifying specific individuals who pose security threats. TSA also receives, on a regular basis, copies of the airmen registry from the FAA.[1] In some cases, individuals identified by other agencies as security threats hold or have applied for airman certificates, ratings, or authorizations, such as pilot certificates, mechanic certificates, and special purpose pilot authorizations, issued by the FAA under 49 U.S.C. Chapter 447. Individuals who pose security threats and hold FAA certificates, ratings, or authorizations are in positions to disrupt the transportation system and harm the public.

In ATSA, Congress specifically required the Under Secretary to establish procedures to notify the FAA Administrator, among others, of the identity of individuals known to pose, or suspected of posing, a threat of air piracy or terrorism, or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). Congress required the FAA Administrator to ''make modifications in the system for issuing airman certificates related to combating acts of terrorism.'' 49 U.S.C. 44703(g).

The Under Secretary has an express mandate to identify and coordinate countermeasures to address threats to the transportation system. In addition, Congress has expressly directed TSA to work with the FAA Administrator with respect to actions that may affect aviation safety or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat. Therefore, TSA is adopting the procedures set forth herein to notify the FAA of a security threat concerning a U.S. citizen who holds or is applying for an FAA certificate, rating, or authorization.

Congress has given the TSA broad powers related to the security of civil aviation, including the authority to receive, assess, and distribute intelligence information related to transportation security. The TSA is charged with serving as the primary liaison for transportation security to the intelligence and law enforcement communities. *See* 49 U.S.C. 114(f)(1) and (5). The Under Secretary is uniquely situated as an expert in transportation security, based on his functions, responsibilities, duties, and powers, to determine whether sufficient cause exists to believe that an individual poses a threat to aviation security. Congress, in ATSA, committed to the TSA's discretion the role of assessing such threats and communicating them to other agencies, including the FAA, for appropriate action.

In ATSA, Congress also created the Transportation Security Oversight Board (TSOB). 49 U.S.C. 115. The members include the Secretary of Transportation, the Attorney General, the Secretary of Defense, the Secretary of the Treasury, and the Director of the Central Intelligence Agency, or such officials' designees, as well as one member appointed by the President to represent the National Security Council and one member appointed by the President to represent the Office of Homeland Security. The Under Secretary is required to consult with the TSOB in establishing procedures for notifying the Administrator of the identity of individuals known to pose, or suspected of posing, a risk of air piracy or terrorism, or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). The Under Secretary has consulted with the TSOB regarding the procedures set forth in this rule.

Discussion of the Final Rule

This final rule adds a new § 1540.115 to 49 CFR part 1540, entitled ''Threat assessments regarding citizens of the United States holding or applying for FAA certificates, ratings, or authorizations.'' New § 1540.115 sets forth the procedure that TSA follows when notifying the FAA of certain individuals who pose a security threat.

Section 1540.115(a) provides that the notification procedure applies when TSA has determined that an individual holding or applying for an FAA airman certificate, rating, or authorization poses a security threat. This rule applies to citizens of the United States. A separate rule published in this **Federal Register** applies to aliens.

Section 1540.115(b) of the final rule sets forth the definitions of certain terms used in the rule, some of which are discussed further below.

Under § 1540.115(c) of the final rule, an individual poses a security threat if the individual is suspected of posing or is known to pose: (1) A threat to transportation or national security; (2) a threat of air piracy or terrorism; (3) a threat to airline or passenger security; or (4) a threat to civil aviation security. This definition is based on 49 U.S.C. 114(f) and (h), which authorize the Under Secretary to identify and counter threats to the transportation system and to communicate information to the FAA regarding individuals who pose a security threat.

While the Under Secretary has been granted full discretion to conduct threat assessments and act upon them, TSA recognizes that notifying the FAA that an individual poses a security threat will have significant consequences. Further, the individual may have information that he or she may wish the Under Secretary to consider in making a final decision. Accordingly, the procedure in this final rule provides an individual with an opportunity to respond before the Under Secretary makes a decision on the threat assessment.

Section 1540.115(d) of this final rule makes clear that the individual may, if he or she so chooses, be represented by counsel, at his or her own expense, in the proceedings described in the final rule.

Section 1540.115(e)(1) provides that if the Assistant Administrator for Intelligence for TSA (Assistant Administrator) determines that an individual poses a security threat, the Assistant Administrator will serve upon that individual an Initial Notification of Threat Assessment and serve it upon the FAA. This Initial Notification will form the basis for the FAA to delay the issuance of or to suspend the individual's certificate, rating, or authorization pending completion of TSA's process.

Section 1540.115(e)(2) provides that not later than 15 calendar days after the date of service of the Initial Notification, the individual may serve a written request for copies of releasable materials upon which the Initial Notification was based.

In this section ''date of service'' has the same meaning as the definition of that term in the Rules of Practice in Transportation Security Administration Civil Penalty Actions and TSA's Investigative and Enforcement Procedures. *See* 49 CFR 1503.211(d). We note that, while § 1503.211(e) of the Rules of Practice also provides for additional time for a party to act after service by mail, this rule incorporates additional time in the stated time frames and no additional time will be added for that purpose under this rule.

Section 1540.115(e)(3) provides that not later than 30 calendar days, or such longer period as TSA may determine for good cause, after TSA receives the individual's request for copies of the releasable materials, TSA will respond.

Under Section 1540.115(e)(4), not later than 15 calendar days after the date of service of the Initial Notification or the date of service of TSA's response to the individual's request for releasable materials, if such a request was made, the individual may serve a written reply to the Initial Notification. The reply may include any information that the individual believes the Under Secretary

[1] The registry is formally known as the ''Comprehensive Airmen Information System.''

should consider in making a final decision.

Section 1540.115(e)(5) provides that not later than 30 calendar days, or such longer period as TSA may determine for good cause, after TSA receives the individual's reply, TSA serves a final decision in accordance with paragraph (f) of this section.

TSA recognizes that this process provides shorter time periods for the individual and TSA to act than in many administrative proceedings. However, recognizing that the individual's certificate, rating, or authorization will be delayed or suspended by the FAA during this period, this procedure is designed to permit TSA to make a final determination quickly, ensuring that the affected individual obtains a prompt review of any issues that are raised. At the same time, TSA is committed to providing adequate process to those individuals who are subject to the procedure. Therefore, this rule provides for three levels of administrative review of TSA's determination that an individual poses a security threat. Unlike the procedure applicable to alien holders of or applicants for certificates, this rule, which applies only to citizens of the United States, provides for a separate review by the Under Secretary. Only after the Under Secretary has reviewed the relevant information and confirmed the two prior determinations of the Assistant Administrator and the Deputy Administrator, is TSA's determination final. This difference between the two rules reflects the greater level of process due to citizens of the United States under law. TSA believes this process provides adequate and appropriate procedural safeguards for the interests of United States citizens.

Under § 1540.115(f), the Deputy Administrator of TSA reviews the Initial Notification of Threat Assessment, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to him. The Deputy Administrator will undertake a de novo review to determine whether the individual poses a security risk.

If the Deputy Administrator determines that the individual poses a security threat, the Under Secretary reviews the Initial Notification, the individual's reply, if any, and any other materials or information available to him. If the Under Secretary determines that the individual poses a security threat, TSA serves upon the individual a Final Notification of Threat Assessment and serves a copy upon the FAA Administrator. The Final Notification includes a statement that the Under Secretary has personally reviewed the Initial Notification, the individual's reply, if any, any other information or materials available to him, and has determined that the individual poses a security threat. This Final Notification will form the basis of the FAA's revocation of, or denial of, the individual's certificate, rating, or authorization.

If the Deputy Administrator does not determine that the individual poses a security threat, or upon review, the Under Secretary does not determine that the individual poses a security threat, TSA serves upon the individual a Withdrawal of the Initial Notification and serves a copy to the FAA.

Section 1540.115(g) provides that in connection with this section, TSA does not disclose to the individual classified information, as defined in Executive Order 12968 section 1.1(d), and TSA reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law, such as sensitive security information (SSI), sensitive law enforcement and intelligence information; sources, methods, means, and application of intelligence techniques; and identities of confidential informants, undercover operatives, and material witnesses.

In most cases, the determination that an individual poses a security threat will be based, in large part or exclusively, on classified national security information, unclassified information designated as SSI, or other information that is protected from disclosure by law, such as the Freedom of Information Act (FOIA). *See* 5 U.S.C 552(b)(1), (2), (7).

Classified national security information is information that the President or another authorized Federal official has determined, pursuant to Executive Order (EO) 12958, must be protected against unauthorized disclosure in order to safeguard the security of American citizens, the country's democratic institutions, and America's participation within the community of nations. *See* E.O. 12958 (60 FR 19825, April 20, 1995). E.O. 12968 prohibits Federal employees from disclosing classified information to individuals who have not been cleared to have access to such information under the requirements of that EO. *See* E.O. 12968 sec. 3.2(a), 6.2(a)(1) (60 FR 40245, Aug. 7, 1995). If the Assistant Administrator has determined that an individual who is the subject of a threat assessment proceeding poses a threat to transportation security, that individual will not be able to obtain a clearance to have access to classified national security information, and TSA has no authority to release such information to that individual.

The denial of access to classified information under these circumstances is consistent with the treatment of classified information under the FOIA, which specifically exempts such information from the general requirement under FOIA that all government documents are subject to public disclosure. *See* 5 U.S.C. 522(b)(1).

SSI is unclassified information that is subject to disclosure limitations under statute and TSA regulations. *See* 49 U.S.C. 114(s); 49 CFR part 1520. Under 49 U.S.C. 114(s), the Under Secretary may designate categories of information as SSI if release of the information would be detrimental to the security of transportation. The SSI designation allows TSA to limit disclosure of this information to people with a need to know in order to carry out regulatory security duties. *See* 49 CFR 1520.5(b).

Among the categories of information that the Under Secretary has defined as SSI by regulation is information concerning threats against transportation. *See* 49 CFR 1520.7(i). Thus, information that TSA obtains indicating that an individual poses a security threat, including the source of such information and the methods through which the information was obtained, will commonly be SSI or classified information. The purpose of designating such information as SSI is to ensure that those who seek to do harm to the transportation system and their associates and supporters do not obtain access to information that will enable them to evade the government's efforts to detect and prevent their activities. Disclosure of this information, especially to an individual specifically suspected of posing a threat to the aviation system, is precisely the type of harm that Congress sought to avoid by authorizing the Under Secretary to define and protect SSI.

Other types of information also are protected from disclosure by law due to their sensitivity in law enforcement and intelligence. In some instances, the release of information about a particular individual or his supporters or associates could have a substantial adverse impact on security matters. The release of the identities or other information regarding individuals related to a security threat determination by TSA could jeopardize sources and methods of the intelligence community, the identities of confidential sources, and techniques and procedures for law enforcement investigations or prosecution. *See* 5

U.S.C 552(b)(7)(D), (E). Release of such information also could have a substantial adverse impact on ongoing investigations being conducted by federal law enforcement agencies, possibly giving a terrorist organization or other group a roadmap of the course and progress of an investigation. In certain instances, release of information could alert a terrorist's coconspirators to the extent of the federal investigation and the imminence of their own detection, thus provoking flight. Those without access to information about the progress of federal investigations are not in a meaningful position and therefore cannot make judgments about the risk of release of information about that investigation that TSA has relied upon in making a security threat determination.

This intelligence ''mosaic'' dilemma has been well recognized by the courts in concluding both that they are ill-suited to second guess the Executive Branch's determination and that seemingly innocuous production should not be made. The business of foreign intelligence gathering in this age of computer technology is more akin to the construction of a mosaic than it is to the management of a cloak-and-dagger affair. Thousands of pieces of seemingly innocuous information can be analyzed and fitted into place to reveal with startling clarity how the unseen whole must operate. The Fourth Circuit Court of Appeals has observed:

> The significance of one item of information may frequently depend upon knowledge of many other items of information. What may seem trivial to the uninformed, may appear of great moment to one who has a broad view of the scene and may put the questioned item of information in its proper context. The courts, of course are ill-equipped to become sufficiently steeped in foreign intelligence matters to serve effectively in the review of secrecy classifications in this area.

United States v. *Marchetti,* 466 F.2d 1309, 1318 (4th Cir.), *cert. denied,* 409 U.S. 1063 (1972). *Halkin* v. *Helms,* 598 F. 2d 1 (D.C. Cir 1978). *See also e.g., Kasza* v. *Browner,* 133 F. 3d 1159, 1166 (9th Cir. 1998) (Quoting Halkin); *J Roderick MacArthur Foundation* v. *Federal Bureau of Investigation,* 102 F.3d 600, 604 (D.C. Cir 1996) (''As we have said before, ''Intelligence gathering is akin to the construction of a mosaic' ''(citation omitted)).

For the reasons discussed above, TSA will not provide to the individual under these procedures any classified information, and TSA reserves the right not to disclose SSI or other sensitive material not warranting disclosure or protected from disclosure under law.

Good Cause for Immediate Adoption

This action is being taken without providing the opportunity for notice and comment, and it provides for immediate effectiveness upon adoption. The Under Secretary has determined this action is necessary to prevent imminent hazard to aircraft, persons, and property within the United States. TSA, after consultation with the FAA, has determined that this action is necessary to minimize security threats and potential security vulnerabilities to the fullest extent possible. The FAA, TSA, and other federal security organizations have been concerned about the potential use of aircraft to carry out terrorist acts in the United States since September 11. This rule codifies the fundamental and inherently obvious principle that a person who TSA determines poses a security threat should not hold an FAA-issued airman certificate.

The Under Secretary finds that notice and comment are unnecessary, impracticable, and contrary to the public interest, pursuant to section 553 of the Administrative Procedure Act (APA). Section 553(b) of the APA permits an agency to forgo notice and comment rulemaking when ''the agency for good cause finds * * * that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest.'' The use of notice and comment prior to issuance of this rule could delay the ability of TSA and the FAA to take effective action to keep persons found by TSA to pose a security threat from holding an airman certificate. Further, the Under Secretary finds that good cause exists under 5 U.S.C. 553(d) for making this final rule effective immediately upon publication. This action is necessary to prevent a possible imminent hazard to aircraft, persons, and property within the United States.

Economic Analyses

Changes to Federal regulations must undergo several economic analyses. First, E.O. 12866 directs each Federal agency to propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

This regulatory evaluation applies to both this rule, which applies to U.S. citizens, and to the corresponding rule, which applies to aliens. While, to date, all individuals whom the Under Secretary has assessed as threats have been aliens, TSA is not able to predict which individuals, who may be subject to TSA threat assessments, may be citizens of the United States or aliens in the future. This regulatory evaluation examines the costs and benefits of TSA notifying the FAA of its assessment that an individual holding or applying for an FAA certificate, rating, or authorization poses a security threat. TSA is taking this action in an ongoing effort to improve national security. The procedure of notification and action taken by the FAA and TSA could prevent aircraft, persons, and property in the United States from imminent peril by the denial or revocation of FAA certificates, ratings, or authorizations of those individuals who pose a security threat.

The Assistant Administrator for Intelligence makes a determination regarding an individual posing a security threat who also holds or is applying for an FAA certificate, rating, or authorization. The Assistant Administrator then issues an Initial Notification to the FAA Administrator and the subject individual. At that time, the individual has the opportunity to act in three ways: (1) Reply and request the materials that the determination is based on; (2) reply without requesting materials; or (3) do nothing. The Deputy Administrator reviews the Initial Notification, and the Under Secretary makes the final review. TSA issues the Final Notification or a Withdrawal of Initial Notification to the FAA Administrator and the subject individual. It is the FAA Administrator who will take action and deny or revoke the FAA certificate, rating, or authorization if the Under Secretary determines that the individual poses a security threat. There are over 3.75 million holders of airmen certificates, ratings, or authorizations, who are subject to this final rule.

TSA has determined that this rule is not, in economic impact, a ''significant regulatory action'' as defined in E.O. 12866, Regulatory Planning and Review, but due to the potential public interest in this rule it is considered to be a ''significant regulatory action'' under

that Executive Order and under the DOT Regulatory Policies and Procedures. TSA determines this final rule does not have a significant economic impact on a substantial number of small entities. Regarding paperwork reduction, there are no new requirements for the collection of information associated with this rule. In terms of international trade, the rule will neither impose a competitive trade disadvantage to U.S. aircraft operators operating overseas nor foreign aircraft operators deplaning or enplaning passengers within the United States. In terms of the Unfunded Mandates Act, the rule will not contain any Federal intergovernmental mandates or private sector mandates.

Introduction and Background

ATSA (49 U.S.C. 114) makes TSA responsible for security in all modes of transportation regulated by DOT, including civil aviation. Additionally, ATSA transferred the duty of ensuring civil aviation security from the FAA to TSA. To carry out its security mission, TSA must assess intelligence and other information in order to identify individuals who pose a threat to security. In doing so, TSA must coordinate with other federal agencies, including the FAA, to address these threats. 49 U.S.C. 114(f)(13) specifically requires TSA to work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations.

While performing the duty of ensuring civil aviation security, TSA receives information from other agencies and other sources identifying particular individuals who pose security threats. In some cases, these individuals hold airman certificates, ratings, or authorizations, such as pilot or mechanic certificates, ratings, or authorizations that were issued by the FAA in accordance with 49 U.S.C. Chapter 447. These individuals who pose security threats and hold FAA certificates, ratings, or authorizations are in positions to disrupt the civil aviation transportation system and harm the public.

In ATSA, Congress specifically required the Under Secretary to establish procedures to notify the FAA Administrator, among others, of the identities of individuals who are known to pose or suspected of posing, a threat of air piracy or terrorism or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). Additionally, in 49 U.S.C. 44703(g), as amended by ATSA section 129, Congress required the FAA Administrator to make modifications to the system used for issuing aviation certificates, ratings, or authorizations in order to make the system more effective in combating acts of terrorism.

The Under Secretary has determined that TSA must notify the FAA when TSA's threat assessment reveals an individual who holds an FAA certificate, rating, or authorization or is an applicant for such certification poses a security threat. This determination is based on the Congressional authorization for the Under Secretary to identify and counter threats to transportation security and Congress's express direction that TSA work with the FAA Administrator in taking actions that may affect aviation security or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat.

Cost of Compliance

TSA has performed an expected cost-benefit analysis for the final rule. To date, from a pool of approximately 1.35 million holders of airmen certificates issued by the FAA in the last ten years, TSA has identified 11 persons who are security threats. Estimating the number of FAA certificates that will be issued in the next ten years, from 2003 to 2012, TSA has found that an estimated nine persons out of an estimated 1.11 million airmen certificates over the ten years will be flagged or at least one person per year. If, however, the estimates are off by as much as a factor of ten, TSA estimates that approximately 100 persons may be impacted over the ten-year period. This estimates equates to ten persons per year over the ten-year period.

This rule allows an impacted party to respond to the TSA-issued Initial Notification in order to refute the finding of the security threat assessment. To date, seven individuals or 63.64 percent from the 11 identified are in the process of responding to a threat assessment notice from TSA. Assuming this percentage will remain relatively constant, TSA calculated a minimum and maximum number of impacted persons who will respond ranging from one person to six persons per year. Using the value of passenger time per hour for general aviation from ''Economic Values for Valuation of Federal Aviation Administration Investment and Regulatory Programs (Values)'' (FAA–APO–98–8) as a proxy for the wage rate of the impacted party, TSA estimated the approximate costs to respond to an Initial Notification without legal counsel to be $31.10 per hour in 2001 dollars. TSA assumed it would take an impacted person five hours to respond to the Initial Notification via a written letter requesting releasable materials upon which the decision was made, review any TSA materials, and write a response based upon these materials. An additional $20 was added to cover any costs of postage, copying, and stationery costs. Therefore, the total estimated cost for an individual to respond to TSA's Initial Notification equals approximately $176 per person in 2001 dollars. If an individual chooses to hire legal counsel, the cost rises to approximately $1000 to $1500 based on five hours legal time at between $200–300 per hour.

TSA projected the costs of this rule for impacted parties over the ten-year period of 2003–2012. The range of one person refuting per year without legal counsel to six persons per year refuting with legal counsel was used for analysis. Costs were discounted over the ten-year period using the standard seven percent discount rate as dictated by the Office of Management and Budget (Circular A–94). The total costs for this rule projected over the next ten years ranges from $1,755 (if one person per year responds on his/her own without legal counsel) to $71,735 (if six persons per year hire legal counsel to respond to findings) in 2001 discounted dollars.

Analysis of Benefits

This rule is intended to enhance aviation security. Congress has mandated that the Under Secretary identify and counter threats to the transportation system and national security, as well as, work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat. The primary benefit of the rule will be increased protection to Americans and others from acts of terrorism. The changes envisioned in this rule are an integral part of the total program needed to prevent a criminal or terrorist incident in the future.

Since the mid-1980s, the major goals of aviation security have been to prevent bombing and sabotage incidents. The individuals covered by this rule hold airman certificates, ratings, or authorizations, such as pilot and mechanic certificates, ratings, or authorizations, issued by the FAA under 49 U.S.C. Chapter 447. These certificates, ratings, or authorizations allow these individuals access to aircraft while in maintenance and repair, to fly aircraft, or to operate aircraft navigational equipment. These individuals are in unique positions to disrupt the civil air transportation system and harm the public through acts of air piracy, sabotage, or misuse of

the aircraft. As such, these individuals could represent a definitive threat to security.

Comparison of Costs and Benefits

It is estimated this rule will have insignificant incurred costs when compared to the potential benefits. The potential benefits are huge in the number of lives and amount of property within the United States saved from a catastrophic terrorist act by this rule. As such, the small amount of costs and the large positive value of the cost-benefit analysis support the rule as cost-beneficial.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) established ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

TSA has determined that this rule will not have a significant economic impact on a substantial number of small entities, pursuant to the RFA, 5 U.S.C. 605(b). This determination is based on the fact that the rule affects only individuals, not entities. Additionally, based on the comparison of costs and benefits set forth above, the costs incurred by individuals will be insignificant compared to potential benefits of the rule. Therefore, pursuant to the RFA, 5 U.S.C. 605(b), TSA certifies that this rule will not have a significant impact on a substantial number of small entities. The FAA has also issued a final rule regarding denial and revocation of FAA-issued certificates, ratings, or authorizations and has determined that such denial or revocation will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the TSA consider the impact of paperwork and other information collection burdens imposed on the public. We have determined that there are no new requirements for information collection associated with this final rule. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid Office of Management and Budget (OMB) control number.

International Trade Impact Statement

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety and security, are not considered unnecessary obstacles. The statute also requires consideration of international standards, and where appropriate, that they be the basis for U.S. standards. The TSA has assessed the potential effect of this rulemaking and has determined that it will have only a domestic impact and, therefore, no effect on any trade-sensitive activity.

Unfunded Mandates Determination

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Pub. L. 104–4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments.

Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.''

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

TSA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Environmental Analysis

TSA has reviewed this action for purposes of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) and has determined that this action will not have a significant effect on the human environment.

Energy Impact

The energy impact of this final rule has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Pub. L. 94–163, as amended (42 U.S.C. 6362). We have determined that this rulemaking is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 49 CFR Part 1540

Air carriers, Aircraft, Airports, Law enforcement officers, Reporting and recordkeeping requirements, Security measures.

The Amendment

In consideration of the foregoing, the Transportation Security Administration amends Chapter XII of Title 49, Code of Federal Regulations, as follows:

PART 1540—CIVIL AVIATION SECURITY: GENERAL RULES

1. The authority citation for part 1540 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40119, 44901–44907, 44913–44914, 44916–44918, 44935–44936, 44942, 46105.

2. Amend part 1540 by adding § 1540.115 to read as follows:

§ 1540.115 Threat assessments regarding citizens of the United States holding or applying for FAA certificates, ratings, or authorizations.

(a) *Applicability.* This section applies when TSA has determined that an individual who is a United States citizen and who holds, or is applying for, an airman certificate, rating, or authorization issued by the Administrator, poses a security threat.

(b) *Definitions.* The following terms apply in this section:

Assistant Administrator means the Assistant Administrator for Intelligence for TSA.

Date of service means—

(1) The date of personal delivery in the case of personal service;

(2) The mailing date shown on the certificate of service;

(3) The date shown on the postmark if there is no certificate of service; or

(4) Another mailing date shown by other evidence if there is no certificate of service or postmark.

Deputy Administrator means the officer next in rank below the Under Secretary of Transportation for Security.

FAA Administrator means the Administrator of the Federal Aviation Administration.

Individual means an individual whom TSA determines poses a security threat.

Under Secretary means the Under Secretary of Transportation for Security.

(c) *Security threat.* An individual poses a security threat when the individual is suspected of posing, or is known to pose—

(1) A threat to transportation or national security;

(2) A threat of air piracy or terrorism;

(3) A threat to airline or passenger security; or

(4) A threat to civil aviation security.

(d) *Representation by counsel.* The individual may, if he or she so chooses, be represented by counsel at his or her own expense.

(e) *Initial Notification of Threat Assessment.* (1) *Issuance.* If the Assistant Administrator determines that an individual poses a security threat, the Assistant Administrator serves upon the individual an Initial Notification of Threat Assessment and serves the determination upon the FAA Administrator. The Initial Notification includes—

(i) A statement that the Assistant Administrator personally has reviewed the materials upon which the Initial Notification was based; and

(ii) A statement that the Assistant Administrator has determined that the individual poses a security threat.

(2) *Request for Materials.* Not later than 15 calendar days after the date of service of the Initial Notification, the individual may serve a written request for copies of the releasable materials upon which the Initial Notification was based.

(3) *TSA response.* Not later than 30 calendar days, or such longer period as TSA may determine for good cause, after receiving the individual's request for copies of the releasable materials upon which the Initial Notification was based, TSA serves a response. TSA will not include in its response any classified information or other information described in paragraph (g) of this section.

(4) *Reply.* The individual may serve upon TSA a written reply to the Initial Notification of Threat Assessment not later than 15 calendar days after the date of service of the Initial Notification, or the date of service of TSA's response to the individual's request under paragraph (e)(2) if such a request was served. The reply may include any information that the individual believes TSA should consider in reviewing the basis for the Initial Notification.

(5) *TSA final determination.* Not later than 30 calendar days, or such longer period as TSA may determine for good cause, after TSA receives the individual's reply, TSA serves a final determination in accordance with paragraph (f) of this section.

(f) *Final Notification of Threat Assessment.* (1) *In general.* The Deputy Administrator reviews the Initial Notification, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to him.

(2) *Review and Issuance of Final Notification.* If the Deputy Administrator determines that the individual poses a security threat, the Under Secretary reviews the Initial Notification, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to him. If the Under Secretary determines that the individual poses a security threat, the Under Secretary serves upon the individual a Final Notification of Threat Assessment and serves the determination upon the FAA Administrator. The Final Notification includes a statement that the Under Secretary personally has reviewed the Initial Notification, the individual's reply, if any, and any other materials or information available to him, and has determined that the individual poses a security threat.

(3) *Withdrawal of Initial Notification.* If the Deputy Administrator does not determine that the individual poses a security threat, or upon review, the Under Secretary does not determine that the individual poses a security threat, TSA serves upon the individual a Withdrawal of the Initial Notification and provides a copy of the Withdrawal to the FAA Administrator.

(g) *Nondisclosure of certain information.* In connection with the procedures under this section, TSA does not disclose to the individual classified information, as defined in Executive Order 12968 section 1.1(d), and reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law.

Issued in Washington, DC on January 21, 2003.

J.M. Loy,

Under Secretary of Transportation for Security.

[FR Doc. 03–1682 Filed 1–22–03; 10:09 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Transportation Security Administration

49 CFR Part 1540

[Docket No. TSA–2002–13733; Amendment No. 1540–4]

RIN 2110–AA17

Threat Assessments Regarding Alien Holders of, and Applicants for, FAA Certificates

AGENCY: Transportation Security Administration (TSA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This final rule establishes the procedure by which TSA will notify the subject individual and the Federal Aviation Administration (FAA) of TSA's assessment that an individual who is an alien and who holds or is applying for an FAA airman certificate, rating, or authorization poses a security threat. This procedure provides such individuals notice and an opportunity to be heard before TSA makes a final decision, while furthering the federal government's important and immediate interest in protecting national security and providing the nation with a safe and secure transportation system.

DATES: Effective on January 24, 2003. Submit comments by March 25, 2003.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number TSA–2002–13733 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that TSA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov.* You may review the public docket containing comments to these regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal

holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Brandon Straus, Office of the Chief Counsel, Transportation Security Administration, 400 Seventh Street, SW., Washington, DC 20590–0001; telephone (202) 493–1224; e-mail: *brandon.straus@tsa.dot.gov.* For information regarding the Economic Analysis, contact Jenny R. Randall, Economist, Office of Security Regulation & Policy, Transportation Security Administration, 400 Seventh Street, SW., Washington, DC 20590–0001; telephone (202) 385–1554; e-mail: *jenny.randall@tsa.dot.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This final rule is being adopted without prior notice and prior public comment. However, the Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 1134; February 26, 1979) provide that, to the maximum extent possible, operating administrations within DOT should provide an opportunity for public comment on regulations issued without prior notice. Accordingly, interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting this amendment. The most helpful comments will reference a specific portion of the rule, explain the reason for any recommended change, and include supporting data. See **ADDRESSES** above for information on how to submit comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with TSA personnel concerning this rulemaking. The docket is available for public inspection before and after the comment closing date.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these rules in light of the comments we receive.

Electronic Access

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page *(http://dms.dot.gov/search);*

(2) Accessing the Government Printing Office's Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html;* or

(3) Visiting the TSA's Laws and Regulations Web page at *http://www.tsa.dot.gov/law_policy/law_policy_index.shtm.*

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this rulemaking.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the TSA to comply with small entity requests for information and advice about compliance with statutes and regulations within the TSA's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in **FOR FURTHER INFORMATION CONTACT**. Persons can obtain further information regarding SBREFA on the Small Business Administration's Web page at *http://www.sba.gov/advo/laws/law_lib.html.*

Background

Following the terrorist attacks on the United States on September 11, 2001, Congress recognized the need for a fundamental change in the federal government's approach to ensuring the security of civil aviation. The September 11 attacks highlighted the fact that the security of the civil aviation system is critical to national security and essential to the basic freedom of Americans to move in intrastate, interstate, and international transportation. *See* H.R. Conf. Rep. 107–296, 107th Cong., 1st Sess. 53 (2001).

In order to address the need for heightened security in civil aviation and other modes of transportation, Congress passed the Aviation and Transportation Security Act (ATSA), Pub. L. 107–71, 115 Stat. 597 (November 19, 2001). ATSA established the TSA within DOT, operating under the direction of the Under Secretary of Transportation for Security (Under Secretary). TSA is responsible for security in all modes of transportation regulated by DOT, including civil aviation. Accordingly, ATSA transferred the responsibility for civil aviation security from the FAA to TSA.

ATSA Requirements

As part of its security mission, TSA is responsible for assessing intelligence and other information in order to identify individuals who pose a threat to transportation security and to coordinate countermeasures with other Federal agencies, including the FAA, to address such threats. *See* 49 U.S.C. 114(f)(1)–(5), (h)(1)–(4). Specifically, Congress required TSA to work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations. 49 U.S.C. 114(f)(13).

In the course of carrying out this responsibility, TSA receives information from other federal agencies and other sources identifying specific individuals who pose security threats. TSA also receives, on a regular basis, copies of the airmen registry from the FAA.[1] In some cases, individuals identified by other agencies as security threats hold or have applied for airman certificates, ratings, or authorizations, such as pilot certificates, mechanic certificates, and special purpose pilot authorizations, issued by the FAA under 49 U.S.C. Chapter 447. Individuals who pose security threats and hold FAA certificates, ratings, or authorizations are in positions to disrupt the transportation system and harm the public.

In ATSA, Congress specifically required the Under Secretary to establish procedures to notify the FAA Administrator, among others, of the identity of individuals known to pose, or suspected of posing, a threat of air piracy or terrorism, or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). Congress required the FAA Administrator to ''make modifications in the system for issuing airman certificates related to combating acts of terrorism.'' 49 U.S.C. 44703(g).

Based on the Under Secretary's express mandate to identify and coordinate countermeasures to address threats to the transportation system, as well as Congress's express direction for TSA to work with the FAA Administrator with respect to actions that may affect aviation safety or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat, TSA is adopting the procedures set forth herein to notify the FAA when TSA's threat assessment reveals that an alien who is an FAA certificate, rating, or authorization holder or applicant poses a security threat.

Congress has given the TSA broad powers related to the security of civil aviation, including the authority to receive, assess, and distribute intelligence information related to

[1] The registry is formally known as the ''Comprehensive Airmen Information System.''

transportation security. The TSA is charged with serving as the primary liaison for transportation security to the intelligence and law enforcement communities. *See* 49 U.S.C. 114(f)(1) and (5). The Under Secretary is uniquely situated as an expert in transportation security, based on his functions, responsibilities, duties, and powers, to determine whether sufficient cause exists to believe that an individual poses a threat to aviation security. Congress, in ATSA, committed to the TSA's discretion the role of assessing such threats and communicating them to other agencies, including the FAA, for appropriate action.

In ATSA, Congress also created the Transportation Security Oversight Board (TSOB). 49 U.S.C. 115. The members include the Secretary of Transportation, the Attorney General, the Secretary of Defense, the Secretary of the Treasury, and the Director of the Central Intelligence Agency, or such officials' designees, as well as one member appointed by the President to represent the National Security Council and one member appointed by the President to represent the Office of Homeland Security. The Under Secretary is required to consult with the TSOB in establishing procedures for notifying the FAA Administrator of the identity of individuals known to pose, or suspected of posing, a risk of air piracy or terrorism, or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). The Under Secretary has consulted with the TSOB regarding the procedures set forth in this rule.

Discussion of the Final Rule

This final rule adds a new § 1540.117 to 49 CFR part 1540, entitled ''Threat assessments regarding aliens holding or applying for FAA certificates, ratings, or authorizations.'' New § 1540.117 sets forth the procedure that TSA follows when notifying the FAA of certain individuals who pose a security threat.

Section 1540.117(a) provides that the notification procedure applies when TSA has determined that an individual holding or applying for an FAA airman certificate, rating, or authorization poses a security threat.

This rule applies to aliens, not to citizens of United States. A separate rule published in this **Federal Register** applies to United States citizens. The agency is not required to afford aliens the same processes afforded to United States citizens who apply for or hold airman certificates. Pursuant to 49 U.S.C. 44703(e), the FAA Administrator may restrict or prohibit issuance of an airman certificate to an alien for any reason. Additionally, the FAA Administrator may make issuing the certificate to an alien dependent on a reciprocal agreement with the government of a foreign country. At this time, TSA has determined that certain aliens pose a security threat, but has not made such a determination as to any U.S. citizen.

As discussed further below, under the final rule the Deputy Administrator of TSA makes the final security threat determination, under a delegation of authority from the Under Secretary. The Deputy Administrator is the officer next in rank below the Under Secretary. Under a rule published separately in this **Federal Register** setting forth TSA's procedures governing security threat determinations for citizens of the United States, the Under Secretary is the final decision maker for threat assessments for those categories of individuals. This difference between the two rules reflects the greater level of process due to citizens of the United States under law.

Section 1540.117(b) of the final rule sets forth the definitions of certain terms used in the rule, some of which are discussed further below.

Under § 1540.117(c) of the final rule, an individual poses a security threat if the individual is suspected of posing or is known to pose: (1) A threat to transportation or national security; (2) a threat of air piracy or terrorism; (3) a threat to airline or passenger security; or (4) a threat to civil aviation security. This definition is based on 49 U.S.C. 114(f) and (h), which authorize the Under Secretary to identify and counter threats to the transportation system and to communicate information to the FAA regarding individuals who pose a security threat.

While TSA has been granted full discretion to conduct threat assessments and act upon them, the agency recognizes that notifying the FAA that an individual poses a security threat will have significant consequences. Further, the individual may have information that he or she may wish TSA to consider in making a final decision. Accordingly, the procedure in this final rule provides an individual with an opportunity to respond before TSA makes a final decision on the threat assessment.

Section 1540.117(d) of this final rule makes clear that the individual may, if he or she so chooses, be represented by counsel at his or her own expense, in the proceedings described in the final rule.

Section 1540.117(e)(1) provides that if the Assistant Administrator for Intelligence for TSA (Assistant Administrator) determines that an individual poses a security threat, the Assistant Administrator will serve upon that individual an Initial Notification of Threat Assessment and serve it upon the FAA. This Initial Notification will form the basis for the FAA to delay the issuance of or to suspend the individual's certificate, rating, or authorization pending completion of TSA's process.

Section 1540.117(e)(2) provides that not later than 15 calendar days after the date of service of the Initial Notification, the individual may serve a written request for copies of releasable materials upon which the Initial Notification was based.

Under § 1540.117(b)(2), ''date of service'' has the same meaning as the definition of that term in the Rules of Practice in Transportation Security Administration Civil Penalty Actions and TSA's Investigative and Enforcement Procedures. *See* 49 CFR § 1503.211(d). We note that, while § 1503.211(e) of the Rules of Practice also provides for additional time for a party to act after service by mail, this rule incorporates additional time in the stated time frames and no additional time will be added for that purpose under this rule.

Section 1540.117(e)(3) provides that not later than 30 calendar days, or such longer period as TSA may determine for good cause, after TSA receives the individual's request for copies of the releasable materials, TSA will respond.

Under Section 1540.117(e)(4), not later than 15 calendar days after the date of service of the Initial Notification or the date of service of TSA's response to the individual's request for releasable materials, if such a request was made, the individual may serve TSA a written reply to the Initial Notification. The reply may include any information that the individual believes TSA should consider in making a final decision.

Section 1540.117(e)(5) provides that not later than 30 calendar days after TSA receives the individual's reply, or such longer period as TSA may determine for good cause, TSA serves a final decision in accordance with paragraph (f) of this section.

TSA recognizes that this process provides shorter time periods for the individual and TSA to act than many administrative proceedings. However, recognizing that the individual's certificate, rating, or authorization will be delayed or suspended by the FAA during this period, this procedure is designed to permit the Deputy Administrator to make a final determination quickly, ensuring that the affected individual obtains a prompt review of any issues that are raised.

Under § 1540.117(f), the Deputy Administrator reviews the Initial Notification of Threat Assessment, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to him. The Deputy Administrator will undertake a *de novo* review to determine whether the individual poses a security risk.

If the Deputy Administrator determines that the individual poses a security threat, TSA serves upon the individual a Final Notification of Threat Assessment and serves a copy upon the Administrator. The Final Notification includes a statement that the Deputy Administrator has personally reviewed the Initial Notification, the individual's reply, if any, and any other materials or information available to him, and has determined that the individual poses a security threat. This Final Notification will form the basis of the FAA's revocation of, or denial of, the individual's certificate, rating, or authorization.

If the Deputy Administrator does not determine that the individual poses a security threat, TSA serves upon the individual a Withdrawal of the Initial Notification and serves a copy upon the FAA.

Section 1540.117(g) provides that in connection with this section, TSA does not disclose to the individual classified information, as defined in Executive Order 12968 section 1.1(d), and TSA reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law, such as sensitive security information (SSI), sensitive law enforcement and intelligence information; sources, methods, means, and application of intelligence techniques, and identities of confidential informants, undercover operatives, and material witnesses.

In most cases, the determination that an individual poses a security threat will be based, in large part or exclusively, on classified national security information, unclassified information designated as SSI, or other information that is protected from disclosure by law, such as the Freedom of Information Act (FOIA). *See* 5 U.S.C 552(b)(1), (2), (7).

Classified national security information is information that the President or another authorized Federal official has determined, pursuant to Executive Order (EO) 12958, must be protected against unauthorized disclosure in order to safeguard the security of American citizens, the country's democratic institutions, and America's participation within the community of nations. *See* E.O. 12958 (60 FR 19825, April 20, 1995). E.O. 12968 prohibits Federal employees from disclosing classified information to individuals who have not been cleared to have access to such information under the requirements of that EO *See* E.O. 12968 sec. 3.2(a), 6.2(a)(1) (60 FR 40245, Aug. 7, 1995). If the Assistant Administrator has determined that an individual who is the subject of a threat assessment proceeding poses a threat to transportation security, that individual will not be able to obtain a clearance to have access to classified national security information, and TSA has no authority to release such information to that individual.

The denial of access to classified information under these circumstances is consistent with the treatment of classified information under the FOIA, which specifically exempts such information from the general requirement under FOIA that all government documents are subject to public disclosure. *See* 5 U.S.C. 522(b)(1).

SSI is unclassified information that is subject to disclosure limitations under statute and TSA regulations. *See* 49 U.S.C. 114(s); 49 CFR part 1520. Under 49 U.S.C. 114(s), the Under Secretary may designate categories of information as SSI if release of the information would be detrimental to the security of transportation. The SSI designation allows TSA to limit disclosure of this information to people with a need to know in order to carry out regulatory security duties. *See* 49 CFR 1520.5(b).

Among the categories of information that the Under Secretary has defined as SSI by regulation is information concerning threats against transportation. *See* 49 CFR 1520.7(i). Thus, information that TSA obtains indicating that an individual poses a security threat, including the source of such information and the methods through which the information was obtained, will commonly be SSI or classified information. The purpose of designating such information as SSI is to ensure that those who seek to do harm to the transportation system and their associates and supporters do not obtain access to information that will enable them to evade the government's efforts to detect and prevent their activities. Disclosure of this information, especially to an individual specifically suspected of posing a threat to the aviation system, is precisely the type of harm that Congress sought to avoid by authorizing the Under Secretary to define and protect SSI.

Other types of information also are protected from disclosure by law due to their sensitivity in law enforcement and intelligence. In some instances, the release of information about a particular individual or his supporters or associates could have a substantial adverse impact on security matters. The release of the identities or other information regarding individuals related to a security threat determination by TSA could jeopardize sources and methods of the intelligence community, the identities of confidential sources, and techniques and procedures for law enforcement investigations or prosecution. *See* 5 U.S.C. 552(b)(7)(D), (E). Release of such information also could have a substantial adverse impact on ongoing investigations being conducted by Federal law enforcement agencies, possibly giving a terrorist organization or other group a roadmap of the course and progress of an investigation. In certain instances, release of information could alert a terrorist's coconspirators to the extent of the Federal investigation and the imminence of their own detection, thus provoking flight. Those without access to information about the progress of federal investigations are not in a meaningful position and therefore cannot make judgments about the risk of release of information about that investigation that TSA has relied upon in making a security threat determination.

This intelligence ''mosaic'' dilemma has been well recognized by the courts in concluding both that they are ill-suited to second guess the Executive Branch's determination and that seemingly innocuous production should not be made. The business of foreign intelligence gathering in this age of computer technology is more akin to the construction of a mosaic than it is to the management of a cloak-and-dagger affair. Thousands of pieces of seemingly innocuous information can be analyzed and fitted into place to reveal with startling clarity how the unseen whole must operate. The Fourth Circuit Court of Appeals has observed:

> ''The significance of one item of information may frequently depend upon knowledge of many other items of information. What may seem trivial to the uninformed, may appear of great moment to one who has a broad view of the scene and may put the questioned item of information in its proper context. The courts, of course are ill equipped to become sufficiently steeped in foreign intelligence matters to serve effectively in the review of secrecy classifications in this area.''

United States versus *Marchetti*, 466 F. 2d 1309, 1318 (4th Cir.), *cert. denied*, 409 U.S. 1063 (1972). *Halkin* versus *Helms,* 598 F. 2d 1 (D.C. Cir. 1978). *See*

also e.g., Kasza versus *Browner*, 133 F. 3d 1159, 1166 (9th Cir. 1998) (Quoting Halkin); *J. Roderick MacArthur Foundation* versus *Federal Bureau of Investigation,* 102 F. 3d 600, 604 (D.C. Cir. 1996) (''As we have said before, 'Intelligence gathering is akin to the construction of a mosaic' '' (citation omitted)).

For the reasons discussed above, TSA will not provide to the individual under these procedures any classified information, and TSA reserves the right not to disclose SSI or other sensitive material not warranting disclosure or protected from disclosure under law.

Good Cause for Immediate Adoption

This action is being taken without providing the opportunity for notice and comment, and it provides for immediate effectiveness upon adoption. The Under Secretary has determined this action is necessary to prevent imminent hazard to aircraft, persons, and property within the United States. TSA, after consultation with the FAA, has determined that this action is necessary to minimize security threats and potential security vulnerabilities to the fullest extent possible. The FAA, TSA, and other federal security organizations have been concerned about the potential use of aircraft to carry out terrorist acts in the United States since September 11. This rule codifies the fundamental and inherently obvious principle that a person who TSA determines poses a security threat should not hold an FAA-issued airman certificate.

The Under Secretary finds that notice and comment are unnecessary, impracticable, and contrary to the public interest, pursuant to section 553 of the Administrative Procedure Act (APA). Section 553(b) of the APA permits an agency to forgo notice and comment rulemaking when ''the agency for good cause finds * * * that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest.'' The use of notice and comment prior to issuance of this rule could delay the ability of TSA and the FAA to take effective action to keep persons found by TSA to pose a security threat from holding an airman certificate. Further, the Under Secretary finds that good cause exists under 5 U.S.C. 553(d) for making this final rule effective immediately upon publication. This action is necessary to prevent a possible imminent hazard to aircraft, persons, and property within the United States.

Economic Analyses

Changes to Federal regulations must undergo several economic analyses. First, E.O. 12866 directs each Federal agency to propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

This regulatory evaluation applies to both this rule, which applies to aliens, and to the corresponding rule, which applies to citizens of the United States. While, to date, all individuals whom the Under Secretary has assessed as threats have been aliens, TSA is not able to predict which individuals, who may be subject to TSA threat assessments, may be citizens of the United States or aliens in the future. This regulatory evaluation examines the costs and benefits of TSA notifying the FAA of its assessment that an individual holding or applying for an FAA certificate, rating, or authorization poses a security threat. TSA is taking this action in an ongoing effort to improve national security. The procedure of notification and action taken by the FAA and TSA could prevent aircraft, persons, and property in the United States from imminent peril by the denial or revocation of FAA certificates, ratings, or authorizations of those individuals who pose a security threat.

The Assistant Administrator for Intelligence makes a determination regarding an individual posing a security threat who also holds or is applying for an FAA certificate, rating, or authorization. The Assistant Administrator then issues an Initial Notification to the FAA Administrator and the subject individual. At that time, the individual has the opportunity to act in three ways: (1) Reply and request the materials that the determination is based on; (2) reply without first requesting the materials, or (3) do nothing. The Deputy Administrator makes the final review and issues the Final Notification or a Withdrawal of Initial Notification to the FAA Administrator and the subject individual. It is the FAA Administrator who will take action and deny or revoke the FAA certificate, rating, or authorization if the Deputy Administrator determines that the individual poses a security threat.

TSA has determined that this rule is not, an economic impact, a ''significant regulatory action'' as defined in E.O. 12866, Regulatory Planning and Review, but due to the potential public interest in this rule it is considered to be a ''significant regulatory action'' under that Executive Order and under the DOT Regulatory Policies and Procedures. TSA determines this final rule does not have a significant economic impact on a substantial number of small entities. Regarding paperwork reduction, there are no new requirements for the collection of information associated with this rule. In terms of international trade, the rule will neither impose a competitive trade disadvantage to U.S. aircraft operators operating overseas nor foreign aircraft operators deplaning or enplaning passengers within the United States. In terms of the Unfunded Mandates Act, the rule will not contain any Federal intergovernmental mandates or private sector mandates.

Introduction and Background

ATSA (49 U.S.C. 114) makes TSA responsible for security in all modes of transportation regulated by DOT, including civil aviation. Additionally, ATSA transferred the duty of ensuring civil aviation security from the FAA to TSA. To carry out its security mission, TSA must assess intelligence and other information in order to identify individuals who pose a threat to security. In doing so, TSA must coordinate with other federal agencies, including the FAA, to address these threats. 49 U.S.C. 114(f)(13) specifically requires TSA to work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations.

While performing the duty of ensuring civil aviation security, TSA receives information from other agencies and other sources identifying particular individuals who pose security threats. In some cases, these individuals hold airman certificates, ratings, or authorizations, such as pilot or mechanic certificates, ratings, or authorizations that were issued by the FAA in accordance with 49 U.S.C. Chapter 447. These individuals who pose security threats and hold FAA certificates, ratings, or authorizations are in positions to disrupt the civil aviation transportation system and harm the public.

In ATSA, Congress specifically required the Under Secretary to

establish procedures to notify the FAA Administrator, among others, of the identities of individuals who are known to pose or suspected of posing, a threat of air piracy or terrorism or a threat to airline or passenger safety. 49 U.S.C. 114(h)(2). Additionally, in 49 U.S.C. 44703(g), as amended by ATSA section 129, Congress required the FAA Administrator to make modifications to the system used for issuing aviation certificates, ratings, or authorizations in order to make the system more effective in combating acts of terrorism.

The Under Secretary has determined that TSA must notify the FAA when TSA's threat assessment reveals an individual who holds an FAA certificate, rating, or authorization or is an applicant for such certification poses a security threat. This determination is based on the Congressional authorization for the Under Secretary to identify and counter threats to transportation security and Congress's express direction that TSA work with the FAA Administrator in taking actions that may affect aviation security or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat.

Cost of Compliance

TSA has performed an expected cost-benefit analysis for the final rule. To date, from a pool of approximately 1.35 million holders of airmen certificates issued by the FAA in the last ten years, TSA has identified 11 persons who are security threats. Estimating the number of FAA certificates that will be issued in the next ten years, from 2003 to 2012, TSA has found that an estimated nine persons out of an estimated 1.11 million airmen certificates over the ten years will be flagged or at least one person per year. If, however, the estimates are off by as much as a factor of ten, TSA estimates that approximately 100 persons may be impacted over the ten-year period. This estimates equates to ten persons per year over the ten-year period.

This rule allows an impacted party to respond to the TSA-issued Initial Notification in order to refute the finding of the security threat assessment. To date, seven individuals or 63.64% from the 11 identified are in the process of responding to a threat assessment notice from TSA. Assuming this percentage will remain relatively constant, TSA calculated a minimum and maximum number of impacted persons who will respond ranging from one person to six persons per year. Using the value of passenger time per hour for general aviation from *Economic Values for Valuation of Federal Aviation Administration Investment and Regulatory Programs (Values)* (FAA–APO–98–8) as a proxy for the wage rate of the impacted party, TSA estimated the approximate costs to respond to an Initial Notification without legal counsel to be $31.10 per hour in 2001 dollars. TSA assumed it would take an impacted person five hours to respond to the Initial Notification via a written letter requesting releasable materials upon which the decision was made, review any TSA materials, and write a response based upon these materials. An additional $20 was added to cover any costs of postage, copying, and stationery costs. Therefore, the total estimated cost for an individual to respond to TSA's Initial Notification equals approximately $176 per person in 2001 dollars. If an individual chooses to hire legal counsel, the cost rises to approximately $1000 to $1500 based on five hours legal time at between $200–300 per hour.

TSA projected the costs of this rule for impacted parties over the ten-year period of 2003–2012. The range of one person refuting per year without legal counsel to six persons per year refuting with legal counsel was used for analysis. Costs were discounted over the ten-year period using the standard seven percent discount rate as dictated by the Office of Management and Budget (Circular A–94). The total costs for this rule projected over the next ten years ranges from $1,755 (if one person per year responds on his/her own without legal counsel) to $71,735 (if six persons per year hire legal counsel to respond to findings) in 2001 discounted dollars.

Analysis of Benefits

This rule is intended to enhance aviation security. Congress has mandated that the Under Secretary identify and counter threats to the transportation system and national security, as well as, work with the FAA Administrator to take actions that may affect aviation safety or air carrier operations and to communicate information to the FAA regarding individuals who pose a security threat. The primary benefit of the rule will be increased protection to Americans and others from acts of terrorism. The changes envisioned in this rule are an integral part of the total program needed to prevent a criminal or terrorist incident in the future.

Since the mid-1980s, the major goals of aviation security have been to prevent bombing and sabotage incidents. The individuals covered by this rule hold airman certificates, ratings, or authorizations, such as pilot and mechanic certificates, ratings, or authorizations, issued by the FAA under 49 U.S.C. Chapter 447. These certificates, ratings, or authorizations allow these individuals access to aircraft while in maintenance and repair, to fly aircraft, or to operate aircraft navigational equipment. These individuals are in unique positions to disrupt the civil air transportation system and harm the public through acts of air piracy, sabotage, or misuse of the aircraft. As such, these individuals could represent a definitive threat to security.

Comparison of Costs and Benefits

It is estimated this rule will have insignificant incurred costs when compared to the potential benefits. The potential benefits are huge in the number of lives and amount of property within the United States saved from a catastrophic terrorist act by this rule. As such, the small amount of costs and the large positive value of the cost-benefit analysis support the rule as cost-beneficial.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) established ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

TSA has determined that this rule will not have a significant economic impact on a substantial number of small entities, pursuant to the RFA, 5 U.S.C.

605(b). This determination is based on the fact that the rule affects only individuals, not entities. Additionally, based on the comparison of costs and benefits set forth above, the costs incurred by individuals will be insignificant compared to potential benefits of the rule. Therefore, pursuant to the RFA, 5 U.S.C. 605(b), TSA certifies that this rule will not have a significant impact on a substantial number of small entities. The FAA has also issued a final rule regarding denial and revocation of FAA-issued certificates, ratings, or authorizations and has determined that such denial or revocation will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the TSA consider the impact of paperwork and other information collection burdens imposed on the public. We have determined that there are no new requirements for information collection associated with this final rule. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid Office of Management and Budget (OMB) control number.

International Trade Impact Statement

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety and security, are not considered unnecessary obstacles. The statute also requires consideration of international standards, and where appropriate, that they be the basis for U.S. standards. The TSA has assessed the potential effect of this rulemaking and has determined that it will have only a domestic impact and, therefore, no effect on any trade-sensitive activity.

Unfunded Mandates Determination

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Pub. L. 104–4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments.

Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.''

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

TSA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications.

Environmental Analysis

TSA has reviewed this action for purposes of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) and has determined that this action will not have a significant effect on the human environment.

Energy Impact

The energy impact of this final rule has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94–163, as amended (42 U.S.C. 6362). We have determined that this rulemaking is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 49 CFR Part 1540

Air carriers, Aircraft, Airports, Law enforcement officers, Reporting and recordkeeping requirements, Security measures.

The Amendment

In consideration of the foregoing, the Transportation Security Administration amends Chapter XII of Title 49, Code of Federal Regulations, as follows:

PART 1540—CIVIL AVIATION SECURITY: GENERAL RULES

1. The authority citation for part 1540 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40119, 44901–44907, 44913–44914, 44916–44918, 44935–44936, 44942, 46105.

2. Amend part 1540 by adding § 1540.117 to read as follows:

§ 1540.117 Threat assessments regarding aliens holding or applying for FAA certificates, ratings, or authorizations.

(a) Applicability. This section applies when TSA has determined that an individual who is not a citizen of the United States and who holds, or is applying for, an airman certificate, rating, or authorization issued by the FAA Administrator, poses a security threat.

(b) *Definitions*. The following terms apply in this section:

Assistant Administrator means the Assistant Administrator for Intelligence for TSA.

Date of service means—

(1) The date of personal delivery in the case of personal service;

(2) The mailing date shown on the certificate of service;

(3) The date shown on the postmark if there is no certificate of service; or

(4) Another mailing date shown by other evidence if there is no certificate of service or postmark.

Deputy Administrator means the officer next in rank below the Under Secretary of Transportation for Security.

FAA Administrator means the Administrator of the Federal Aviation Administration.

Individual means an individual whom TSA determines poses a security threat.

(c) *Security threat*. An individual poses a security threat when the individual is suspected of posing, or is known to pose—

(1) A threat to transportation or national security;

(2) A threat of air piracy or terrorism;

(3) A threat to airline or passenger security; or

(4) A threat to civil aviation security.

(d) *Representation by counsel*. The individual may, if he or she so chooses, be represented by counsel at his or her own expense.

(e) *Initial Notification of Threat Assessment*. (1) *Issuance*. If the Assistant Administrator determines that an individual poses a security threat, the Assistant Administrator serves upon the individual an Initial Notification of Threat Assessment and serves the determination upon the FAA Administrator. The Initial Notification includes—

(i) A statement that the Assistant Administrator personally has reviewed the materials upon which the Initial Notification was based; and

(ii) A statement that the Assistant Administrator has determined that the individual poses a security threat.

(2) *Request for materials*. Not later than 15 calendar days after the date of service of the Initial Notification, the individual may serve a written request for copies of the releasable materials upon which the Initial Notification was based.

(3) *TSA response*. Not later than 30 calendar days, or such longer period as TSA may determine for good cause, after receiving the individual's request

for copies of the releasable materials upon which the Initial Notification was based, TSA serves a response. TSA will not include in its response any classified information or other information described in paragraph (g) of this section.

(4) *Reply*. The individual may serve upon TSA a written reply to the Initial Notification of Threat Assessment not later than 15 calendar days after the date of service of the Initial Notification, or the date of service of TSA's response to the individual's request under paragraph (e)(2) if such a request was served. The reply may include any information that the individual believes TSA should consider in reviewing the basis for the Initial Notification.

(5) *TSA final determination*. Not later than 30 calendar days, or such longer period as TSA may determine for good cause, after TSA receives the individual's reply, TSA serves a final determination in accordance with paragraph (f) of this section.

(f) *Final Notification of Threat Assessment*. (1) *In general*. The Deputy Administrator reviews the Initial Notification, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to him.

(2) *Issuance of Final Notification*. If the Deputy Administrator determines that the individual poses a security threat, the Deputy Administrator serves upon the individual a Final Notification of Threat Assessment and serves the determination upon the FAA Administrator. The Final Notification includes a statement that the Deputy Administrator personally has reviewed the Initial Notification, the individual's reply, if any, and any other materials or information available to him, and has determined that the individual poses a security threat.

(3) *Withdrawal of Initial Notification*. If the Deputy Administrator does not determine that the individual poses a security threat, TSA serves upon the individual a Withdrawal of the Initial Notification and provides a copy of the Withdrawal to the FAA Administrator.

(g) *Nondisclosure of certain information*. In connection with the procedures under this section, TSA does not disclose to the individual classified information, as defined in Executive Order 12968 section 1.1(d), and TSA reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law.

Issued in Washington, DC, on January 21, 2003.

J.M. Loy,

Under Secretary of Transportation for Security.

[FR Doc. 03–1683 Filed 1–22–03; 10:09 am]

BILLING CODE 4910–62–P

Federal Register

Friday,
January 24, 2003

Part VII

Department of Transportation

14 CFR Parts 61, et al.
Ineligibility for an Airman Certificate Based on Security Grounds; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 63, and 65

[Docket No.: FAA–2003–14293; Amendment Nos. 61–108, 63–32, 65–44]

RIN 2120–AH84

Ineligibility for an Airman Certificate Based on Security Grounds

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This final rule expressly makes a person ineligible to hold FAA-issued airman certificates if the Transportation Security Administration notifies the FAA in writing that the person poses a security threat. This action is intended to reduce the opportunity for persons to carry out terrorist acts in the aviation environment.

DATES: Effective January 24, 2003. Submit comments by March 25, 2003.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590. You must identify the docket number FAA–2003–14293 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that the FAA received your comments, include a self-addressed, stamped postcard. You may also submit comments through the Internet to *http://dms.dot.gov.*

You may review the public docket containing comments to these regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. You may also review public dockets on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Peter J. Lynch, Enforcement Division, AGC–300, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; Telephone No. (202) 267–3137.

SUPPLEMENTARY INFORMATION:

Comments Invited

This final rule is being adopted without prior notice and prior public comment. The Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 1134; Feb 26, 1979) provide that, to the maximum extent possible, operating administrations for the DOT should provide an opportunity for public comment on regulations issued without notice. Accordingly, interested persons are invited to participate in the rulemaking by submitting written data, views, or arguments. Comments relating to the environmental, energy, federalism, or economic impact that might result from these amendments also are invited. Comments must include the docket number or amendment number and must be submitted in duplicate to the address above. All comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking, will be filed in the public docket. The docket is available for public inspection before and after the comment closing date.

The FAA will consider all comments received on or before the closing date for comments. Late-filed comments will be considered to the extent practicable. The final rule may be amended in light of the comments received.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by taking the following steps:

(1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) Web page *(http://dms.dot.gov/search).*

(2) On the search page type in the last four digits of the Docket number shown at the beginning of this notice. Click on ''search.''

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the document number for the item you wish to view.

You can also get an electronic copy using the Internet through the Office of Rulemaking's Web page at *http://www.faa.gov/avr/armhome.htm* or the Government Printing Office's Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

You can also get a copy by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the amendment number or docket number of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT.** You can find out more about SBREFA on the Internet at our site, *http://www.faa.gov/avr/arm/sbrefa.htm.* For more information on SBREFA, e-mail us *9–AWA–SBREFA@faa.gov.*

Background

In response to the tragic events of September 11, 2001, Congress enacted and the President signed the Aviation and Transportation Security Act (ATSA), Public Law 107–71. This law created the Transportation Security Administration (TSA) under the direction of the Under Secretary of Transportation for Security. The Under Secretary is charged with responsibility for civil aviation security as well as security in other modes of transportation. Among other responsibilities, the Under Secretary is to receive, assess, and distribute intelligence information related to transportation security and to assess threats to transportation. The ATSA also directs the Under Secretary to establish procedures to notify the FAA Administrator of the identity of persons known to pose, or suspected of posing, a risk of air piracy or terrorism or a threat to airline or passenger safety.

The ATSA directs the Administrator to make modifications to the system for issuing airman certification to make the system more effective in serving the needs of officials responsible for enforcing laws related to combating acts of terrorism.

The Under Secretary receives information from intelligence sources that identify specific individuals who pose a security risk. In some cases, these individuals hold airman certificates issued by the FAA. On August 14, 2002, the Under Secretary advised the Administrator of 11 such individuals and asked the Administrator to revoke the airman certificates held by them. On August 20, the FAA took the requested action by issuing emergency orders of revocation. These orders became effective immediately.

By rulemakings published today in the **Federal Register**, the TSA has put in place processes for notifying an

individual that he or she has been determined to pose a security threat and to advise the FAA of its determination. One process applies to citizens of the United States, the other to aliens. Under both procedures, the individual is served with an Initial Notification of Threat Assessment when the TSA's Assistant Administrator for Intelligence has concluded that the individual poses a security threat. The individual may respond in writing to this notification and provide any information the individual believes the TSA should consider. In the case of an alien, if the TSA's Deputy Administrator finds that the person does pose a security threat, he or she issues a Final Notification of Threat Assessment. If the Deputy Administrator does not determine that the individual poses a security threat, he or she issues a Withdrawal of Initial Notification. In the case of a U.S. citizen, the Under Secretary will also review the matter before a Final Notification of Threat Assessment is issued. If the Under Secretary determines that the individual poses a security threat, the Under Secretary issues a Final Notification of Threat Assessment. If the Deputy Administrator or Under Secretary does not find that the person poses a threat, the TSA issues a Withdrawal of Initial Notification. At the time the TSA issues its notifications, the FAA is advised of the TSA's determinations with regard to individuals who hold or are applying for an airman certificate.

Once the TSA has determined that a person poses a security threat, that person should not hold an airman certificate authorizing him or her to be in a position that could be used to take actions that are contrary to civil aviation security and, therefore, safety in air commerce. Airmen are in a position to exercise the privileges of their certificates in support of terrorist activities. For example, pilots could drop chemical or biological agents from an aircraft or, as the events of September 11 demonstrated, crash aircraft into buildings. Mechanics could sabotage aircraft, and flight instructors could teach terrorists how to operate aircraft. While a person might attempt to undertake such actions even if he or she does not hold an airman certificate, taking action to deny, suspend, or revoke airman certification is intended to make it more difficult to do so. In any event, persons determined by the TSA to pose a security threat are simply unqualified to hold airman certificates.

The FAA is adding a section to 14 CFR parts 61, 63, and 65 to expressly make individuals who pose a security threat as determined by the TSA ineligible to hold certificates, ratings, and authorizations issued under those parts. This ineligibility means that the FAA will not issue a certificate, rating, or authorization to any applicant who the TSA advises the FAA poses a security threat. If the TSA issues an Initial Notification of Threat Assessment to an applicant, the FAA will hold in abeyance the application pending the outcome of the TSA's final threat assessment review. If an individual is issued a Final Notification of Threat Assessment, the FAA will deny an application for any airman certificate, rating, or authorization.

With regard to certificates already issued, the FAA will suspend an individual's airman certificates after receiving the Initial Notification of Threat Assessment from the TSA. Suspension is appropriate in this circumstance, because the TSA's initial assessment that an individual poses a security threat is still subject to review by the TSA's Deputy Administrator, and, for U.S. citizens, the Under Secretary, and may be reversed. If a Final Notification of Threat Assessment is issued, the FAA will revoke the certificates; if an Initial Notification is withdrawn, the FAA will withdraw its certificate suspension.

The eligibility standards adopted in this rulemaking rely on the threat assessments made by the TSA. This reliance is based on the broad statutory authority and responsibility that the ATSA placed in the Under Secretary with regard to intelligence information and threat assessments.

The Rule Change

The FAA is adding a new section, § 61.18, Security Disqualification, to 14 CFR part 61. This rule states that a person is not eligible to hold a certificate, rating, or authorization issued under part 61 when the TSA has advised the FAA in writing that the person poses a security threat. The TSA's initial finding that a person poses a security threat is contained in an Initial Notification of Threat Assessment; a final finding is contained in a Final Notification of Threat Assessment. The rule explains the effect of the issuance by the TSA of each document. The FAA will hold in abeyance an application by an individual who has been issued an Initial Notification pending the outcome of the TSA's final threat assessment review. If the TSA withdraws its Initial Notification, the FAA will issue a certificate provided the applicant is otherwise qualified. The FAA will suspend certificates held by any person who is initially found by the TSA to pose a security threat. The FAA will withdraw its certificate suspension if the TSA withdraws its Initial Notification. With regard to issuance of a Final Notification of Threat Assessment, the FAA will deny the application of any person to whom the TSA issues a Final Notification of Threat Assessment, and it will revoke any airman certificates held by such a person. New sections 63.14 and 65.14 are being added to 14 CFR parts 63 and 65; they are identical to section 61.18.

Justification for Immediate Adoption

This action is being taken without providing the opportunity for prior notice and comment, and it provides for immediate effectiveness upon adoption. The Administrator has determined this action is necessary to prevent a possible imminent hazard to aircraft, persons, and property within the United States. The FAA, after consultation with the TSA, has determined that this action is necessary to minimize security threats and potential security vulnerabilities to the fullest extent possible. The FAA, TSA, and other federal security organizations have been concerned about the potential use of aircraft to carry out terrorist acts in the United States since September 11. The FAA now believes it is appropriate to provide expressly by rule that an individual determined by the TSA to be a security threat is ineligible for airman certification. This rule thus codifies the fundamental and inherently obvious principle that a person who poses a security threat should not hold an FAA-issued airman certificate.

The FAA finds that notice and comment are unnecessary, impracticable, and contrary to the public interest, pursuant to section 553 of the Administrative Procedure Act (APA). Section 553(b) of the APA permits an agency to forgo notice and comment rulemaking when ''the agency for good cause finds * * * that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest.'' The use of notice and comment prior to issuance of this rule could delay the ability of the FAA to take effective action to keep persons found by the TSA to pose a security threat from holding an airman certificate. Further, the Administrator finds that good cause exists under 5 U.S.C. 553(d) for making this final rule effective immediately upon publication. This action is necessary to prevent a possible imminent hazard to aircraft, persons, and property within the United States.

Paperwork Reduction Act

There are no new requirements for information collection associated with this amendment. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Executive Order 12866 and DOT Regulatory Policies and Procedures

This rulemaking action is taken under an emergency situation within the meaning of Section 6(a)(3)(D) of Executive Order 12866, Regulatory Planning and Review. It also is considered an emergency regulation under Paragraph 11g of the Department of Transportation (DOT) Regulatory Policies and Procedures. The FAA has not separately prepared a regulatory analysis or evaluation of this rule. However, the TSA has prepared a regulatory evaluation for its rulemaking and we do not believe that this action adds any separate costs not already covered by that evaluation. Based on that evaluation, the FAA determines that this rulemaking action is a significant rule within the meaning of the Executive Order and DOT's policies and procedures. Further, the FAA certifies that this final rule does not have a significant economic impact on a substantial number of small entities.

Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this rulemaking and has determined that it will impose no cost on international entities and thus has a neutral trade impact.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104–4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.''

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 3132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we determined that this final rule does not have federalism implications.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of this action has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94–163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Parts 61, 63, and 65

Aircraft, Airmen, Aviation safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations as follows:

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

1. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

2. Add § 61.18 to subpart A to read as follows:

§ 61.18 Security disqualification.

(a) *Eligibility standard.* No person is eligible to hold a certificate, rating, or authorization issued under this part when the Transportation Security Administration (TSA) has notified the FAA in writing that the person poses a security threat.

(b) *Effect of the issuance by the TSA of an Initial Notification of Threat Assessment.* (1) The FAA will hold in abeyance pending the outcome of the TSA's final threat assessment review an application for any certificate, rating, or authorization under this part by any person who has been issued an Initial Notification of Threat Assessment by the TSA.

(2) The FAA will suspend any certificate, rating, or authorization issued under this part after the TSA issues to the holder an Initial Notification of Threat Assessment.

(c) *Effect of the issuance by the TSA of a Final Notification of Threat Assessment.* (1) The FAA will deny an application for any certificate, rating, or authorization under this part to any person who has been issued a Final Notification of Threat Assessment.

(2) The FAA will revoke any certificate, rating, or authorization issued under this part after the TSA has issued to the holder a Final Notification of Threat Assessment.

PART 63—CERTIFICATION: FLIGHT CREWMEMBERS OTHER THAN PILOTS

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

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

4. Add § 63.14 to subpart A to read as follows:

§ 63.14 Security disqualification.

(a) *Eligibility standard.* No person is eligible to hold a certificate, rating, or authorization issued under this part when the Transportation Security Administration (TSA) has notified the FAA in writing that the person poses a security threat.

(b) *Effect of the issuance by the TSA of an Initial Notification of Threat Assessment.* (1) The FAA will hold in abeyance pending the outcome of the TSA's final threat assessment review an application for any certificate, rating, or authorization under this part by any person who has been issued an Initial Notification of Threat Assessment by the TSA.

(2) The FAA will suspend any certificate, rating, or authorization issued under this part after the TSA issues to the holder an Initial Notification of Threat Assessment.

(c) *Effect of the issuance by the TSA of a Final Notification of Threat Assessment.* (1) The FAA will deny an application for any certificate, rating, or authorization under this part to any person who has been issued a Final Notification of Threat Assessment.

(2) The FAA will revoke any certificate, rating, or authorization issued under this part after the TSA has issued to the holder a Final Notification of Threat Assessment.

PART 65—CERTIFICATION: AIRMEN OTHER THAN FLIGHT CREWMEMBERS

5. The authority citation for part 65 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

6. Add § 65.14 to subpart A to read as follows:

§ 65.14 Security disqualification.

(a) *Eligibility standard.* No person is eligible to hold a certificate, rating, or authorization issued under this part when the Transportation Security Administration (TSA) has notified the FAA in writing that the person poses a security threat.

(b) *Effect of the issuance by the TSA of an Initial Notification of Threat Assessment.* (1) The FAA will hold in abeyance pending the outcome of the TSA's final threat assessment review an application for any certificate, rating, or authorization under this part by any person who has been issued an Initial Notification of Threat Assessment by the TSA.

(2) The FAA will suspend any certificate, rating, or authorization issued under this part after the TSA issues to the holder an Initial Notification of Threat Assessment.

(c) *Effect of the issuance by the TSA of a Final Notification of Threat Assessment.* (1) The FAA will deny an application for any certificate, rating, or authorization under this part to any person who has been issued a Final Notification of Threat Assessment.

(2) The FAA will revoke any certificate, rating, or authorization issued under this part after the TSA has issued to the holder a Final Notification of Threat Assessment.

Issued in Washington, DC on January 21, 2003.

Marion C. Blakey,

Administrator.

[FR Doc. 03–1681 Filed 1–22–03; 10:09 am]

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Federal Register

Friday,
January 24, 2003

Part VIII

Department of Transportation

Federal Aviation Administration

14 CFR Parts 71, et al.

Special Operating Rules for the Conduct of Instrument Flight Rules (IFR) Area Navigation (RNAV) Operations Using Global Positioning Systems (GPS) in Alaska; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 71, 91, 95, 121, 125, 129, and 135

[Docket No. FAA–2003–14305; Special Federal Aviation Regulation No. 97]

RIN 2120–AH93

Special Operating Rules for the Conduct of Instrument Flight Rules (IFR) Area Navigation (RNAV) Operations Using Global Positioning Systems (GPS) in Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: Under this Special Federal Aviation Regulation, the FAA proposes to allow the use of Global Positioning System/Wide Area Augmentation Systems for the en route portion of flights on routes in Alaska outside the operational service volume of ground based navigation aids. The use of aircraft navigation equipment other than area navigation systems, that only permit navigation to or from ground-based navigation stations, often results in less than optimal routes or instrument procedures and an inefficient use of airspace. This SFAR would optimize routes and instrument procedures and provide for a more efficient use of airspace. Further, it would result in an associated increase in flight safety.

DATES: Send your comments on or before February 24, 2003.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number, FAA–2003–14305, at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that the FAA received your comments, include a self-addressed, stamped postcard. You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing comments to these proposed regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Donald W. Streeter, Flight Technologies and Procedures Division (AFS–400), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 385–4567; e-mail: *donald.w.streeter@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments received, as well as a report summarizing each substantive public contact made with FAA personnel concerning this proposed rulemaking. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also review the docket using the Internet at the web address in the **ADDRESSES** section.

Before acting on this proposal, we will consider all comments received on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments received.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents through the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(2) Visiting the Office of Rulemaking's Web page at *http://www.faa.gov/avr/armhome.htm*; or

(3) Accessing the **Federal Register**'s Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

You also can get a copy by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number or notice number of this rulemaking.

Background

Aviation is critical to Alaska for routine travel and commerce, and for nearly any kind of emergency. Only 10% of Alaska is accessible by road, and waterways are impassable most of each year. Alaska also is very large and crisscrossed by mountains that block radio and radar transmissions so that aviation services and infrastructure that are available in the 48 contiguous states are not available in many areas of Alaska. Aviation is essential to Alaska, but there also is a safety consequence of operating in this environment: The aviation accident rate for rural Alaska is 2.5 times the average for the rest of the United States. While approximately 20 airports in Alaska are serviced by large turbine and jet aircraft, scheduled and unscheduled air carrier service using single or light-twin engine aircraft that are often limited to visual flight rules operations is provided to approximately 1000 other airports and landing areas. Pilots operating these flights often face weather hazards—fog, ice-fog, white-out or flat-light conditions that are localized and change rapidly. Weather information is limited; there are few navigational aids; and radar coverage is largely unavailable below 5,000 feet. Areas of intense icing and short distances between destinations often keep flight operations below 2,000 feet.

The Capstone Program is a joint initiative by the FAA Alaskan Region and the aviation industry to improve safety and efficiency in Alaska by using new technologies. Derived from the National Transportation Safety Board (NTSB) and industry recommendations, Capstone was congressionally funded in October 1998, and under the FAA Acquisition and Management System, operations and maintenance funding will begin in 2004.

Capstone Phase I focuses on southwest Alaska (the Yukon and Kuskokwim River Delta—YK Delta), which is isolated, has limited infrastructure, and has the same high rate of aviation accidents experienced in the rest of the state. Under Capstone, installation of advanced avionics in the YK Delta aircraft began in November 1999 and expansion of ground infrastructure and data collection will continue through December 2004. An interim analysis by the University of

Alaska and The MITRE Corporation Center for Advanced Aviation System Development indicates a 40 percent reduction in aircraft accidents that are instrument flight rules equipped under the Capstone program verses aircraft that are unequipped.

Relying on lessons learned during Phase I, Capstone Phase II is beginning in southeast Alaska. A more robust set of avionics, that include Global Positioning Systems/Wide Area Augmentation Systems (GPS/WAAS), is being deployed that aims at further reduction of controlled flight into terrain and mid-air collision accidents. In addition, instrument flight rules (IFR) area navigation (RNAV) procedures are being introduced that enable participants to conduct IFR operations on published routes, improving overall safety and capacity.

Area navigation (RNAV) systems used in most aircraft operations consist of a navigation computer, a coded database containing preloaded ground-based navigational aids, instrument approach procedures, standard departure procedures, and standard arrival routes to certain terminal areas. The navigation computer can also be manually loaded to input the latitude and longitude of certain fixes defining an area navigation route. RNAV systems also have the capability of processing transmitted signals from various kinds of navigation aids to continuously update the accuracy of the navigation computer in the lateral and vertical modes of operation. Unlike aircraft very high frequency omnidirectional range (VOR) navigation systems, for example, RNAV systems can be programmed to navigate directly to any geographic reference point (latitude and longitude) on the earth without having to navigate to or from ground-based VOR stations over published routes that are defined by ground-based VOR stations.

The current operating rules under the Federal Aviation Regulations in title 14 of the Code of Federal Regulations (14 CFR) do not accommodate the use of GPS/WAAS technology for IFR RNAV outside the operational service volume of ground-based navigation aids. This SFAR would allow the timely approval of approximately 200 aircraft that are being equipped under Capstone Phase II to conduct IFR RNAV operations using GPS/WAAS navigation systems. Additionally, this SFAR would provide the opportunity for air carrier and general aviation operators, other than those participating in the Capstone Program, to voluntarily equip aircraft with advanced GPS/WAAS avionics that are manufactured, certified, and approved for IFR RNAV operations.

Statement of the Problem

A significant number of mid-air collisions, controlled flight into terrain, and weather-related accidents occur in Alaska. These accidents can be significantly reduced by the use of new aircraft navigation technologies such as GPS/WAAS IFR RNAV systems. However, operating rules under the current FAA regulations do not fully accommodate the use of GPS/WAAS technology for IFR RNAV operations. While a review of national operating rules continues in order to fully accommodate RNAV operations for the National Airspace System (NAS), a timely SFAR needs to be issued because initial GPS/WAAS avionics equipage is scheduled in Alaska between December 2002 and April 2003 under the FAA Capstone Phase II Program.

NTSB Recommendation: Recommendation A–95–121 From NTSB Safety Study

In 1995, the NTSB conducted a study (NTSB Safety Study—Aviation Safety in Alaska, NTSB/SS–95/03, November 1995) to examine ''Alaska's current aviation environment and air transportation activities, to identify the associated risk factors and safety deficiencies, and to recommend practical measures for managing the risks to safe flight operations given the reality of Alaska's aviation environment and the potential of new technologies.'' The following is a NTSB recommendation (A–95–121) from this safety study that substantiates the need for this SFAR.

Implement, by December 31, 1997, a model program in the Arctic and southeast regions of Alaska to demonstrate a low altitude instrument flight rules (IFR) system that better fulfills the needs of Alaska's air transportation system. The model should include the following components:

(1) The use of the global positioning system (GPS) as a sole source of navigational information for en route navigation and for nonprecision instrument approaches at a representative number of airports where instrument approaches do not currently exist. (Operators participating in the program will have to be allowed to conduct these operations without the integrity monitoring functions of the wide area augmentation system (WAAS) until WAAS is fully implemented in the demonstration region.)

(2) The use of satellite-based voice communications and satellite-based, Mode S, or VHF data link (for aircraft position and altitude) between aircraft in flight and air traffic controllers.

(3) The operation of commercial, passenger-carrying flight under IFR in turbine-powered single-engine airplanes equipped with redundant sources of electrical power and gyroscopic instrument vacuum/pressure.

(4) The use of currently uncontrolled airspace for IFR departures, en route flight, and instrument approaches in the demonstration program region. (Class II, Priority Action) (A–95–121).

Reference Material: (1) Technical Standard Order (TSO) C145a, Airborne Navigation Sensors Using The Global Positioning System (GPS) Augmented By The Wide Area Augmentation System (WAAS); and (2) TSO C146a, Stand-Alone Airborne Navigation Equipment Using The Global Positioning System (GPS) Augmented By The Wide Area Augmentation System (WAAS). Copies of these TSOs may be obtained from the FAA Internet Web site at *http://www.faa.gov/certification/aircraft/TSOA.htm*.

Related Activity

The FAA is conducting a thorough review of its rules to ensure consistency between the operating rules of 14 CFR and future RNAV operations for the NAS. That rulemaking, when proposed and promulgated, should enable the use of space-based navigation aid sensors for aircraft RNAV systems through all phases of flight (departure, en route, arrival, and approach) to enhance the safety and efficiency of the NAS. The changes anticipated would result in greater flexibility in air traffic routing, instrument approach procedure design, and airspace use than is now possible with a ground-based navigation aid system structure. The improved navigation accuracy and flexibility would enhance both system capacity and overall flight safety, and would promote the ''free flight'' concept in the NAS by enabling the NAS to move away from reliance on ground-based NAVAIDs. This SFAR supports this activity as an early implementation effort.

Contrary Provisions of the Current Regulations

People who conduct operations in Alaska in accordance with this SFAR would be excepted from certain provisions of the FAA's regulations. For instance:

14 CFR 71.75. Extent of Federal airways. The extent of Federal airways is currently referenced as a center line that extends from one navigational aid or intersection to another navigational aid or intersection specified for that airway. This SFAR allows the Federal airway and other routes published by the FAA to be referenced and defined by one or more fixes that are contained in an RNAV system's electronic database that is derived from GPS satellites and used by the pilot to accurately fly the Federal airway or other published

routes without reference to the ground based navigational aids that defines those routes.

14 CFR 91.181. Course to be flown. Section 91.181 defines courses to be flown along Federal airways that are only referenced to station referenced navigational aids or fixes defining that route. This SFAR would allow courses to be flown on Federal airways and other published routes that are defined by waypoints or fixes contained in a GPS WAAS navigation system that is certified for IFR navigation.

14 CFR 91.205(d)(2). Powered civil aircraft with standard category U.S. airworthiness certificates: Instrument and equipment requirements. Section 91.205(d)(2) states that navigational equipment appropriate to the ground facilities to be used is required for IFR operations and does not include RNAV equipment. Under this SFAR, operations can be conducted using navigation equipment that is not dependent on navigating only to and from ground-based radio navigation stations.

14 CFR 91.711(c)(1)(ii) and 91.711(e). Special rules for foreign civil aircraft. Section 91.711(c)(1)(ii) requires foreign civil aircraft operating within the United States and conducting IFR operations to be equipped with radio navigational equipment appropriate to the navigational signals to be used and does not accommodate the use of RNAV systems for instrument flight rules operations. Section 91.711(e) states that no person may operate a foreign civil aircraft within the 50 states and the District of Columbia at or above flight level (FL) 240 unless the aircraft is equipped with distance measuring equipment (DME) capable of receiving and indicating distance information from the VORTAC facilities to be used. Although an IFR approved RNAV system provides distance information, this section does not allow the use of an RNAV system in lieu of DME.

14 CFR 95.1. Applicability. Part 95 prescribes altitudes governing the operation of aircraft under IFR on Federal airways, jet routes, area navigation low or high routes, or other direct routes for which a minimum enroute altitude (MEA) is designated. In addition, it designates mountainous areas and changeover points. In general, the IFR altitudes prescribed in this section are determined by a route analysis based on the following factors: (1) An obstacle clearance assessment; (2) the lowest altitude at which the aircraft radio navigation receivers are able to receive the ground-based radio navigation fixes defining the airway, segment or route; and (3) the lowest altitude at which two-way voice communication between the aircraft and the air traffic control unit can be maintained. No accommodation is made for IFR altitudes determined by the above route analysis factors over routes that may be defined by fixes other than ground-based navigation aid fixes. Under this SFAR, operators using IFR certified GPS/WAAS RNAV systems would be permitted to conduct operations over routes in Alaska at the lowest minimum en route altitude based only on route obstacle assessments and ATC two-way voice communication capability. This MEA is defined as the ''special MEA'' for purposes of this SFAR to distinguish it from MEAs established under part 95.

14 CFR 121.349(a). Radio equipment for operations under VFR over routes not navigated by pilotage or for operations under IFR or over-the-top. Section 121.349(a) requires airplanes to be equipped with two independent radio navigation systems that are able to receive radio navigational signals from all primary en route and approach navigational facilities intended to be used. This section does not allow, nor does any other section of part 121, allow the use of RNAV GNSS for IFR navigation on Federal airways and other routes. This SFAR allows the use of IFR-certified RNAV GPS/WASS systems for IFR navigation.

14 CFR 125.203(b) and (c). Radio and navigational equipment. These sections state that no person may operate an airplane over-the-top or under IFR unless it has two independent receivers for navigation that are able to receive radio signals from the ground facilities to be used and which are capable of transmitting to, and receiving from, at any place on the route to be flown, at least one ground facility. These sections do not allow the use of RNAV GNSS for IFR navigation for any airplanes conducting IFR operations under part 125 in the NAS. This SFAR would allow for the use of IFR-certified RNAV GPS/WAAS systems for IFR navigation.

14 CFR 129.17(a) and (b). Radio Equipment. Sections 129.17(a) and (b) state that subject to the applicable laws and regulations governing ownership and operation of radio equipment, each foreign air carrier shall equip its aircraft with such radio equipment as is necessary to properly use the air navigation facilities. This section does not include or allow IFR RNAV GNSS to be used for air navigation on Federal airways or other published routes. This SFAR would allow the use of IFR-certified RNAV GPS/WAAS systems for air navigation on Federal airways or other published routes.

14 CFR 135.165. Radio and navigational equipment: Extended overwater or IFR operations. Section 135.165 excludes turbojet airplanes with 10 or more passenger seats, multiengine airplanes in a commuter operations, as defined under 14 CFR part 119, and other aircraft from conducting IFR or extended overwater operations unless they have a minimum of two independent receivers for navigation appropriate to the facilities to be used that are capable of transmitting to, and receiving from, at any place on the route to be flown, at least one ground facility. Since IFR-certified RNAV GPS/WAAS systems do not receive navigation position information from ground facilities, they would not be acceptable for navigation based on this section. This SFAR would allow the use of IFR-certified RNAV GPS/WAAS systems in lieu of aircraft navigation equipment that is used to navigate to and from ground-based navigation facilities.

Section-by-Section Discussion of the Proposal

SFAR No. 97—Special Operating Rules for the Conduct of Instrument Flight Rules (IFR) Area Navigation (RNAV) Operations Using Global Positioning Systems (GPS) in Alaska

Section 1. *Purpose, use and limitations.* The purpose of Section 1 is to define the specific GNSS equipment that is authorized for IFR RNAV operations on Federal airways and other published routes in the airspace in the state of Alaska. This section also states that the SFAR can be used for U.S. and foreign operations conducted under part 91 over Alaska, as well as operations conducted by part 119 or part 125 certificate holders and part 129 operations specifications holders, commercial, and certificated air carrier operators.

Section 2. *Definitions and abbreviations.* The purpose of Section 2 is to define specific terms that are used in this SFAR. These definitions and abbreviations are specific to this SFAR. Some of these definitions may not be defined or consistent with similar definitions in the current Federal Aviation Regulations.

For the purposes of this SFAR, the definition of ''area navigation (RNAV)'' is broadened by removing the words ''station-referenced navigation signals,'' which refer to ground-based signals, and adding the words ''flight path'' to cover operations in both the lateral and vertical planes (*i.e.*, lateral navigation (LNAV) and vertical navigation (VNAV)).

To distinguish MEAs that are established by ground-based navigation aids versus MEAs that are established outside the operational service volume of ground-based navigation aids, the terms ''standard MEA'' and ''special MEA'' are included. As discussed earlier under 14 CFR part 95, the lowest altitude that an aircraft under IFR may be operated is determined by, among other things, the lowest altitude at which the aircraft radio navigation receivers are able to receive ground-based radio navigation fixes defining the airway segment or route. For purposes of this SFAR, this MEA is referenced as the ''standard MEA.'' Operators in Alaska using IFR certified GPS/WAAS RNAV systems (as set forth in the definition of ''required navigation system''), however, would be permitted to conduct operations over routes in or near Alaska based on route obstacle assessments and ATC two-way voice communication capability. This MEA may be lower than the ''standard MEA'' for purposes of this SFAR.

Section 3. *Operational requirements.* The purpose of Section 3 is to establish personnel training and qualifications, and GPS/WAAS performance and signal requirements necessary for operational approval to conduct IFR RNAV operations. This section allows operators subject to this SFAR to operate over routes where the MEA for a route or route segment is lower for GPS/WAAS IFR RNAV-equipped aircraft than the MEA for operators equipped only with VOR navigation systems. This flexibility would allow those GPS/WAAS IFR RNAV-equipped operators to conduct operations at the lowest permissible altitude in an attempt to avoid in-flight icing conditions.

Air carrier operators are required to establish training curriculums that must be reviewed, validated, and approved by the FAA prior to being authorized to conduct IFR RNAV operations for the en route portion of flight at MEAs outside the service volume of ground-based navigation aids under this SFAR. Title 14 CFR part 91 operators also are required to receive training prior to conducting IFR RNAV operations under this SFAR. The part 91 operator is responsible to ensure this training is accomplished. Training programs may be provided by the GPS WAAS avionics manufacturer/distributor. Training material also may be obtained from the FAA Capstone Program Office in Anchorage Alaska.

Section 3 also requires all operators to use authorized procedures for normal, abnormal, and emergency situations unique to these operations, including degraded navigation capabilities, and satellite system outages. Detailed guidance material for these procedures will be provided in the IFR regional supplemental (*e.g.*, pre-flight planning consideration of satellite outages, operational procedures for the loss of RNAV during the operation).

Section 4. *Equipment Requirements.* The purpose of Section 4 is to establish the minimum GPS/WAAS equipment requirements for IFR RNAV operations. TSO C145a and TSO C146a GPS WAAS navigation systems are the systems authorized to be used as the only means of navigation on Federal airways and other published routes outside the operational service volume of ground based navaids in Alaska. The MEA's for these routes will be depicted on the published Low Altitude and High Altitude En Route Charts and depicted as a MEA–G. For example, a GPS MEA of 4000 feet MSL would be depicted using a blue color as: *4000G.*

Section 5. *Expiration date.* The purpose of Section 5 is to establish the time period that this SFAR remains in effect. This SFAR would remain in effect until cancelled or revised.

Parts 71, 95, 121, 125, 129, and 135—Amended

A note would be also added to parts 71, 95, 121, 125, 129, and 135 to cross reference SFAR No. 97, the full text of which would appear in part 91.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there are no current new information collection requirements associated with this proposed rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

Economic Evaluation

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs each Federal agency to propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards, and, where appropriate, that they be the basis for U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

In conducting these analyses, the FAA determined that this proposed rule: (1) Would generate benefits and not impose any costs, is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (2) would not have a significant economic impact on a substantial number of small entities; (3) would not constitute a barrier to international trade, and does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector.

For regulations with an expected minimal impact, the above-specified analyses are not required. The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If it is determined that the expected impact is so minimal that the proposal does not warrant a full evaluation, a statement to that effect and the basis for it is included in proposed regulation. This proposed rule would allow the use of GSP/WAAS for IFR RNAV procedures by locally based aircraft that are equipped under the Alaska Capstone Phase II test and evaluation program. Because there is no cost to the participants for the equipment or training, the expected outcome is expected to have a minimal impact on the flying public in Alaska. This proposed SFAR would also provide the opportunity for other air carrier and general aviation operators to voluntarily equip and train their personnel at their own expense. The decision to incur these costs would be gauged against the safety and efficiency benefits accruing

from IFR RNAV use of GPS/WAAS technology. The FAA requests comments with supporting justification regarding the FAA determination of minimal impact.

Regarding benefits, the adoption of this proposal would implement the National Transportation Safety Board's recommendation ''to demonstrate a low altitude instrument flight rules (IFR) system that better fulfills the needs of Alaska's air transportation system.'' [1] An interim assessment of the safety impact of Capstone Phase 1 test program found that ''while the rates of accidents for specific causes have not changed in a way that is statistically significant yet, the over-all accident counts for the equipped and non-equipped groups were different: 12 accidents for non-equipped versus 7 for equipped even though each had nearly identical operations counts.'' [2] In addition to the anticipated safety benefits, the proposed rule might result in cost savings. The use of IFR RNAV equipment permits the use of more direct and therefore shorter routes, and aircraft using RNAV equipment may require less fuel and time to reach their destinations. The FAA has established a number of test routes throughout the United States and some airlines have estimated annual cost savings in excess of $30 million dollars due to flying these advanced RNAV routes.[3] The FAA finds that the potential safety benefits and cost savings justify the adoption of this proposed rule. The FAA seeks public comments regarding these benefits and cost savings.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule would have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This proposed rule would establish the minimum equipment and operational approval requirements that operators would have to comply with to operate at lower MEAs that are outside the service volume of ground-based navigation aids. Because operators are not required to operate at these lower MEAs, those who voluntarily decide to do so under this SFAR will have made their own business decisions that the cost associated with this proposed SFAR's equipment and other requirements are worth it. For example, some operators will have concluded that flying at lower altitudes opens up markets that they could not previously have served because currently they do not have aircraft that can fly at certain altitudes on some routes and maintain reception with ground-based navigation aids. Other operators will conclude that having the ability to operate at lower MEAs will result in fewer flight cancellations or delays due to adverse weather (*e.g.*, icing at higher altitudes). Additionally, other operators will recognize the safety benefit of having RNAV-equipped aircraft and flightcrews trained under this SFAR when such flights encounter adverse weather conditions en route at higher altitudes. Those operators will have the safety benefit of being able to seek clearance to the lower MEAs en route. It is anticipated that most of the participants who volunteer to participate in Capstone Phase II will not incur any costs to equip their aircraft or conduct required training; therefore, the FAA certifies that the rule will not have a significant economic impact on a substantial number of small operators. The FAA seeks public comments regarding this cost finding.

Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The NPRM proposes to impose requirements on foreign air carriers operating in the SFAR area if they volunteer to participate in the test program. These requirements would mirror the communication and navigation equipment requirements placed on domestic carriers that volunteer to participate in the test program. The FAA assessed the potential effect of this proposed rule and determined that it would have a neutral impact on foreign trade and, therefore, creates no obstacles to the foreign commerce of the United States.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.''

This proposed rule does not contain such a mandate. The requirements of title II do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore would not have federalism implications.

Regulations Affecting Interstate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the Administrator, when modifying regulations under title 14 of the CFR that affect interstate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish such regulatory distinctions as he or she considers appropriate. The FAA considers that this rule will be

[1] Aviation Safety In Alaska (NTSB/SS–95/03) November 1995 page 77.

[2] The Safety Impact of Capstone Phase 1 (W. Worth Kirkman, Mitre) August 2002 page 15.

[3] 2001 ACE Plan, Building Capacity.

beneficial to operations in Alaska, but specifically solicits comments on this issue.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this proposed rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94–163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. We have determined that the notice is not a major regulatory action under the provisions of the EPCA.

List of Subjects

14 CFR Part 71

Airspace, Navigation (air).

14 CFR Part 91

Agriculture, Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Canada, Freight, Mexico, Noise control, Political candidates, Reporting and recordkeeping requirements.

14 CFR Part 95

Air traffic control, Airspace, Alaska, Navigation (air), Puerto Rico.

14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Charter flights, Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 125

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 129

Air carriers, Aircraft, Aviation safety, Reporting and recordkeeping requirements, Security, Smoking.

14 CFR Part 135

Air taxis, Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter I of Title 14, Code of Federal Regulations, as follows:

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

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

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

2. Amend part 71 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

PART 91—GENERAL OPERATING AND FLIGHT RULES

3. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 stat. 1180).

4. Amend part 91 by adding SFAR No. 97 to read as follows:

Special Federal Aviation Regulation No. 97—Special Operating Rules for the Conduct of Instrument Flight Rules (IFR) Area Navigation (RNAV) Operations Using Global Positioning Systems (GPS) in Alaska

Those persons identified in Section 1 may conduct IFR en route RNAV operations in the State of Alaska and its airspace on published air traffic routes using TSO C145a/C146a navigation systems as the only means of IFR navigation. Despite contrary provisions of parts 71, 91, 95, 121, 125, and 135 of this chapter, a person may operate aircraft in accordance with this SFAR if the following requirements are met.

Section 1. Purpose, use, and limitations.

a. This SFAR permits TSO C145a/C146a GPS (RNAV) systems to be used for IFR en route operations in the United States airspace over and near Alaska (as set forth in paragraph c of this section) at Special Minimum En Route Altitudes (MEA) which are outside the operational service volume of ground-based navigation aids, if the aircraft operation also meets the requirements of sections 3 and 4 of this SFAR.

b. Certificate holders and part 91 operators may operate aircraft under this SFAR provided that they comply with the requirements of this SFAR.

c. Operations conducted under this SFAR are limited to United States Airspace within and near the State of Alaska as defined in the following area description:

From 62°00′00.000″N, Long. 141°00′00.00″W.; to Lat. 59°47′54.11″N., Long. 135°28′38.34″W.; to Lat. 56°00′04.11″N., Long. 130°00′07.80″W.; to Lat. 54°43′00.00″N., Long. 130°37′00.00″W.; to Lat. 51°24′00.00″N., Long. 167°49′00.00″W.; to Lat. 50°08′00.00″N., Long. 176°34′00.00″W.; to Lat. 45°42′00.00″N., Long. −162°55′00.00″E.; to Lat. 50°05′00.00″N., Long. −159°00′00.00″E.; to Lat. 54°00′00.00″N., Long. −169°00′00.00″E.; to Lat. 60°00′00.00″N., Long. −180°00′00.00″E; to Lat. 65°00′00.00″N., Long. 168°58′23.00″W.; to Lat. 90°00′00.00″N., Long. 00°00′0.00″W.; to Lat. 62°00′00.000″N, Long. 141°00′00.00″W.

(d) No person may operate an aircraft under IFR during the en route portion of flight below the standard MEA or at the special MEA unless the operation is conducted in accordance with sections 3 and 4 of this SFAR.

Section 2. *Definitions and abbreviations.* For the purposes of this SFAR, the following definitions and abbreviations apply.

Area navigation (RNAV). RNAV is a method of navigation that permits aircraft operations on any desired flight path.

Area navigation (RNAV) route. RNAV route is a published route based on RNAV that can be used by suitably equipped aircraft.

Certificate holder. A certificate holder means a person holding a certificate issued under part 119 or part 125 of this chapter or holding operations specifications issued under part 129 of this chapter.

Global Navigation Satellite System (GNSS). GNSS is a world-wide position and time determination system that uses satellite ranging signals to determine user location. It encompasses all satellite ranging technologies, including GPS and additional satellites. Components of the GNSS include GPS, the Global Orbiting Navigation Satellite System, and WAAS satellites.

Global Positioning System (GPS). GPS is a satellite-based radio navigational, positioning, and time transfer system. The system provides highly accurate position and velocity information and precise time on a continuous global basis to properly equipped users.

Minimum crossing altitude (MCA). The minimum crossing altitude (MCA) applies to the operation of an aircraft proceeding to a higher minimum en route altitude when crossing specified fixes.

Required navigation system. Required navigation system means navigation equipment that meets the performance

requirements of TSO C145a/C146a navigation systems certified for IFR en route operations.

Route segment. Route segment is a portion of a route bounded on each end by a fix or NAVAID.

Special MEA. Special MEA refers to the minimum en route altitudes, using required navigation systems, on published routes outside the operational service volume of ground-based navigation aids and are depicted on the published Low Altitude and High Altitude En Route Charts using the color blue and with the suffix ''G.'' For example, a GPS MEA of 4000 feet MSL would be depicted using the color blue, as 4000G.

Standard MEA. Standard MEA refers to the minimum en route IFR altitude on published routes that uses ground-based navigation aids and are depicted on the published Low Altitude and High Altitude En Route Charts using the color black.

Station referenced. Station referenced refers to radio navigational aids or fixes that are referenced by ground based navigation facilities such as VOR facilities.

Wide Area Augmentation System (WAAS). WAAS is an augmentation to GPS that calculates GPS integrity and correction data on the ground and uses geo-stationary satellites to broadcast GPS integrity and correction data to GPS/WAAS users and to provide ranging signals. It is a safety critical system consisting of a ground network of reference and integrity monitor data processing sites to assess current GPS performance, as well as a space segment that broadcasts that assessment to GNSS users to support en route through precision approach navigation. Users of the system include all aircraft applying the WAAS data and ranging signal.

Section 3. *Operational Requirements.*

To operate an aircraft under this SFAR, the following requirements must be met:

a. Training and qualification for operations and maintenance personnel on required navigation equipment used under this SFAR.

b. Use authorized procedures for normal, abnormal, and emergency situations unique to these operations, including degraded navigation capabilities, and satellite system outages.

c. For certificate holders, training of flight crewmembers and other personnel authorized to exercise operational control on the use of those procedures specified in paragraph b of this section.

d. Part 129 operators must have approval from the State of the operator to conduct operations in accordance with this SFAR.

e. In order to operate under this SFAR, a certificate holder must be authorized in operations specifications.

Section 4. *Equipment Requirements.*

a. The certificate holder must have properly installed, certificated, and functional dual required navigation systems as defined in section 2 of this SFAR for the en route operations covered under this SFAR.

b. When the aircraft is being operated under part 91, the aircraft must be equipped with at least one properly installed, certificated, and functional required navigation system as defined in section 2 of this SFAR for the en route operations covered under this SFAR.

Section 5. *Expiration date.*

This Special Federal Aviation Regulation will remain in effect until rescinded.

PART 95—IFR ALTITUDES

5. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, and 14 CFR 11.49 (b)(2).

6. Amend part 95 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

9. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44901, 44903–44904, 44912, 46105.

10. Amend part 121 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE; AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

11. The authority citation for part 125 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722.

12. Amend part 125 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

PART 129—OPERATIONS: FOREIGN AIR CARRIERS AND FOREIGN OPERATORS OF U.S.-REGISTERED AIRCRAFT ENGAGED IN COMMON CARRIAGE

13. The authority citation for part 129 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40104–40105, 40113, 40119, 41706, 44701–44702, 44712, 44716–44717, 44722, 44901–44904, 44906.

14. Amend part 129 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

PART 135—OPERATIING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

15. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g) 41706, 44113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

16. Amend part 135 by adding a note to read as follows:

Note: For the text of SFAR No. 97, see part 91 of this chapter.

Issued in Washington, DC on January 16, 2003.

James J. Ballough,

Director, Flight Standards Service.

[FR Doc. 03–1601 Filed 1–23–03; 8:45 am]

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Federal Register

Friday,
January 24, 2003

Part IX

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 402

Department of the Interior

Fish and Wildlife Service

50 CFR Part 402

Environmental Protection Agency

40 CFR Chapter I

Endangered Species and Pesticide Regulation; Proposed Rules

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

RIN 0648–AQ69

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 402

RIN 1018–AI95

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[OPP–2003–0010; FRL–7287–3]

RIN 2070–AD72

Endangered Species and Pesticide Regulation

AGENCIES: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce; and Environmental Protection Agency.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This Advance Notice of Proposed Rulemaking (ANPR) announces the intention of the Fish and Wildlife Service (FWS), a bureau of the Department of the Interior, and the National Marine Fisheries Service (NMFS), an Agency of the National Oceanic and Atmospheric Administration (NOAA), jointly referred to as ''the Services,'' in cooperation with the U.S. Environmental Protection Agency (EPA), to conduct rulemaking to promulgate ''counterpart regulations'' under the Endangered Species Act (ESA). Specifically, this ANPR focuses on regulations and policies affecting the process for consultation between EPA and the Services regarding EPA actions in its pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and does not address processes among the Services and any other office within EPA. Throughout this rulemaking process, the Services and EPA will work with the U.S. Department of Agriculture (USDA) to implement the purposes of ESA and to effectuate the intent of the Congress that ESA compliance for EPA's FIFRA program be designed to ''minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.'' This ANPR also seeks public comment on possible approaches to changing the current regulations, policies, and practices of EPA and the Services to better integrate the FIFRA and ESA processes and to improve the efficiency and effectiveness of consultations on pesticide actions to enhance protection of species that are Federally listed or proposed as threatened or endangered and their proposed or designated critical habitat. The agencies are specifically requesting comments that focus on developing solutions to the extremely complex issues surrounding these consultations. In addition, this ANPR seeks comment on ways to improve public involvement and understanding of these processes and the decisions that result from them.

DATES: Comments, identified by docket ID number OPP–2003–0010, must be received on or before March 10, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: *For FWS*: Richard E. Sayers, Jr., Endangered Species Program, U.S. Fish and Wildlife Service, ARL SQ42, 1849 C St., NW., Washington, DC 20240; telephone number: (703) 358–2106; fax number: (703) 358–1735; e-mail address: Rick_Sayers@fws.gov.

For NOAA: Laurie Allen, Office of Protected Resources, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Rm. 13821, Silver Spring, MD; telephone number: (301) 713–2322, fax number: (301) 713–0376; e-mail address: Laurie.Allen@noaa.gov.

For EPA: Arthur-Jean Williams, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5239; fax number: (703) 308–3259; e-mail address: williams.arty@epa.gov.

SUPPLEMENTARY INFORMATION: This ANPR is organized into four Units. Unit I. contains ''General Information'' about the applicability of this ANPR, how to obtain additional information, how to submit comments in response to the request for comments, and certain other related matters. Unit II. provides background information on the pesticide regulatory program and the process by which Federal agencies consult or confer with the FWS and NMFS to ensure appropriate protection of Federally listed and proposed, threatened and endangered species (''listed species'') and their proposed and designated critical habitat (''critical habitat''). It also explains why EPA and the Services are considering changing the current approach to consultation for EPA's pesticide regulatory program and the goals of any future changes. Unit III. of the ANPR identifies specific aspects of the existing consultation process followed by EPA and the Services and seeks public comment on how these aspects might be modified to improve the consultation process for EPA's pesticide regulatory program. Finally, Unit IV. discusses regulatory assessment requirements.

I. General Information

While this ANPR is being issued jointly by EPA and the Services, because EPA has an electronic docket system that allows distribution of materials more easily to interested persons, EPA has agreed to take responsibility for all of the administrative duties related to publication of this document, including the creation of a public docket, receipt of public comments, and other related matters. EPA will share all comments it receives with the Services, and all three agencies will work together to compile and analyze public comments and on any future steps.

A. Does this Action Apply to Me?

This action is directed to the public in general and may be of particular interest to persons who manufacture, sell or use pesticides or who are part of a State or Tribe engaged in the regulation of pesticide products and to groups interested in environmental regulation. The Agency and the Services have 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 Arthur-Jean Williams at the telephone number/e-mail address listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0010. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is

restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA and the Services are not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0010. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2003–0010. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0010.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0010. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.A.1.

D. How Should I Submit CBI to EPA?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that

information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments?

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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action are the Agencies Taking?

The Fish and Wildlife Service (FWS) of the Department of the Interior and the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), together with the Environmental Protection Agency (EPA), announce their intent to conduct rulemaking to make changes in the way that EPA consults with FWS and NMFS (jointly referred to as ''the Services'') under the Endangered Species Act (ESA) on regulatory actions involving pesticides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Services and EPA are issuing this ANPR, in consultation with the U.S. Department of Agriculture (USDA), to solicit public comment on a range of possible changes that are intended to better integrate the consultation process under section 7 of ESA with the process for pesticide regulatory actions taken by EPA under FIFRA, and to improve the efficiency and effectiveness of consultation on pesticide actions. Some of the possible changes would require modification of the Services' existing consultation regulations in 50 CFR part 402; a rule modifying the consultation regulations for a specific Federal agency is called a ''counterpart regulation.'' See 50 CFR 402.04. Other possible changes in the current approach to consultations between EPA and the Services could be accomplished without rulemaking, for example through a Memorandum of Understanding or changes in policies and practices at EPA or the Services.

EPA and the Services are currently engaged in a number of separate, but related activities relative to EPA's responsibilities under ESA, in addition to the publication of this ANPR. First, under ESA section 7(a)(1), EPA and the Services are engaged in an ongoing Proactive Conservation Review. This review of EPA's Endangered Species Protection Program (ESPP) is intended to clarify for the involved Federal agencies EPA's approach to risk assessment, criteria that indicate a listed species may be at risk, and the requirements imposed on EPA by the ESA regulations governing consultation. The review will also identify areas or issues relative to risk assessment, criteria, and consultations that may require modification to enhance the effectiveness and efficiency of consultation among EPA and the Services. While this review is conducted under ESA section 7(a)(1), the outcomes of the review will likely be used to help focus discussions on technical and science policy issues that need to be addressed to carry out responsibilities under ESA section 7(a)(2) more effectively and efficiently. Second, on December 2, 2002, EPA published a Notice in the **Federal Register** (67 FR 71549) (FRL–7283–7) describing and requesting comments on implementation of its ESPP. The goal of the ESPP is to carry out EPA's responsibilities under FIFRA in compliance with ESA, while at the same time not placing unnecessary burden on agriculture and other pesticide users.

Although this ANPR contemplates significant revisions to the Services' ESA regulations as they relate to EPA's pesticide regulatory programs under FIFRA, EPA will continue to address its ESA section 7(a)(2) obligations regarding pesticide actions under existing Service rules until such time as the changes contemplated by this ANPR are finalized. While EPA and the Services believe these revisions can greatly improve the efficiency and effectiveness of the consultation process, all three agencies believe that the work they will be doing under the existing regulations during this interim period will ensure that endangered species are protected as required by law.

EPA and the Services believe it is also important that the public and pesticide registrants and users understand that EPA has significant authority under FIFRA to protect endangered species and their habitats from potentially harmful exposure to pesticides, and that FIFRA provides EPA the exclusive statutory authority for modifying a pesticide registration. Accordingly, when regulatory action is determined to be appropriate to protect listed species or their habitat, EPA will use the authority and procedures set forth in FIFRA to undertake such action.

B. What are the Agencies' Authorities for Taking this Action?

This ANPR is issued under the authority of section 7 of the Endangered Species Act (ESA), as amended, 16 U.S.C. 1531 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA's statutory authority and programs for regulating pesticides are discussed in Unit II.C., while Unit II.D., describes the applicable provisions of ESA and implementing regulations.

C. FIFRA and Pesticide Regulation

FIFRA is the primary statute under which EPA regulates the use of pesticides in the United States. 7 U.S.C. 136 *et seq.* FIFRA defines a ''pesticide'' as ''. . . any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . . .'' FIFRA sec. 2(u). When a pesticide is sold or distributed, it is generally referred to as a ''pesticide product.'' Pesticides contain both ''active ingredients'' and ''inert ingredients.'' An ''active ingredient'' is ''. . . an ingredient which will prevent, destroy, repel, or mitigate any pest . . . .'' FIFRA sec. 2(a). Ingredients which are not active are referred to as

''inert ingredients'' or ''other ingredients.'' Under FIFRA, an ''inert ingredient'' is defined as ''an ingredient which is not active.'' FIFRA sec. 2(m). EPA uses the term, ''formulation,'' to refer to the particular combination of active and inert ingredients in a pesticide product. A pesticide ''use'' refers to the particular combination of circumstances under which a pesticide product may be applied, such as the rate, timing, method, and site of application.

1. *The statutory framework for regulation of new pesticide products.* FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been ''registered'' by EPA. FIFRA sec. 12(a)(1)(A). EPA issues a license, referred to as a ''registration,'' for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific product labeling for a specific use. Each product is evaluated on a case-by-case basis.

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed product meets the statutory standard. EPA may approve the unconditional registration of a pesticide product only if the Agency determines, among other things, that use of the pesticide would not cause ''unreasonable adverse effects on the environment.'' FIFRA sec. 3(c)(5). The statute defines ''unreasonable adverse effects on the environment'' to include ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . . .'' FIFRA sec. 2(bb).

When EPA registers a pesticide, it approves among other things a specific set of labeling for the product which contains directions for and restrictions on use of the product. Labeling includes any written or graphic material attached to the product container, i.e., the label, as well as other material accompanying the product or referenced on the label. FIFRA sec. 2(p). FIFRA makes it unlawful for any person ''to use any registered pesticide in a manner inconsistent with its labeling.'' FIFRA sec. 12(a)(2)(G). Thus, directions and restrictions appearing on, or referenced in, a pesticide product label become enforceable Federal requirements. Under FIFRA, most States have primary responsibility for enforcement against pesticide misuse. See FIFRA sec. 26.

While most regulatory decisions allowing entry of new pesticide products into the marketplace are made by EPA in its registration program, there are two other programs that can authorize the use of new pesticides. Under section 18 of FIFRA, EPA may allow the use of an unregistered pesticide product by a State or Federal agency when necessary to address an emergency situation. Under EPA's regulations, a petition for an exemption must establish that ''emergency conditions'' -- defined as ''an urgent, non-routine situation that requires the use of a pesticide . . .'' -- exist and that no effective, currently registered pesticide or non-pesticidal pest control method is available. 40 CFR 166.4(d). The emergency exemption regulations provide that EPA will not approve a request unless EPA determines, among other things, the use of the pesticide product will not cause unreasonable adverse effects on the environment. 40 CFR 166.25(b). In addition, under certain limited circumstances, States may approve a new use of a currently registered pesticide product to meet a ''special local need.'' FIFRA sec. 24(c). EPA's regulations limit States' exercise of this authority only to the approval of products that contain active ingredients that are present in a currently approved pesticide product and give EPA broad authority to disapprove products intended for uses that are not closely related to existing uses. See 40 CFR 162.152. States must notify EPA when they exercise this authority and a State's registration shall not be effective for more than 90 days if disapproved by EPA within that period. FIFRA sec. 24(c)(2).

2. *The statutory framework for regulation of existing pesticide products.* In addition to a registration program for new pesticide products, EPA conducts a ''reregistration'' program. Reregistration focuses on currently registered pesticides and involves a systematic reexamination of the scientific data to determine whether the pesticides continue to meet contemporary scientific and regulatory standards. See FIFRA sec. 4. Among other things, EPA assesses whether there are adequate data to determine if the statutory standard is met. FIFRA gives EPA authority to require registrants to provide data if EPA ''determines [the] additional data are required to maintain in effect an existing registration of a pesticide.'' FIFRA sec. 3(c)(2)(B). (Imposition of such additional data requirements is subject to the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 - 3520). In the past, EPA has used this authority to require registrants to conduct studies that would provide additional data needed for the evaluation of potential hazards of and exposures to pesticide products. EPA uses such data to assess pesticide risks and to determine whether changes in the terms and conditions of registration would be appropriate. In many cases, EPA's reregistration review has concluded that additional risk mitigation measures were necessary to reduce potential harm to non-target plants and wildlife populations. Many registrants voluntarily have amended their products' registrations to implement these risk mitigation measures. If, however, registrants do not adopt needed risk mitigation, EPA may impose the requirements through cancellation or suspension proceedings, conducted pursuant to FIFRA sec. 6 and 40 CFR part 164.

EPA may issue a Notice of Intent to Cancel the registration of a pesticide if it appears that the continued use of the pesticide ''generally causes unreasonable adverse effects on the environment.'' FIFRA sec. 6(b). Thus, the standard for approving a pesticide's entry into the marketplace and the standard for retaining a pesticide on the market is based on a determination relative to ''no unreasonable adverse effects'' Because cancellation proceedings can be lengthy, FIFRA also contains provisions allowing EPA to ''suspend'' the registration and use of a pesticide, prior to the completion of a cancellation process, if use of the pesticide poses an ''imminent hazard.'' FIFRA sec. 6(c). FIFRA defines an ''imminent hazard'' as ''a situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened under [the Endangered Species Act].'' FIFRA sec. 2(l).

3. *Ecological risk assessment.* In deciding whether a pesticide product meets the statutory standards for registration or reregistration, EPA considers, among other things, the potential risks to non-target wildlife and plant species posed by use of the pesticide product. EPA's evaluation of such environmental risks follows the principles contained in its Guidelines for Ecological Risk Assessment. (EPA 1998). In 1986, EPA developed detailed guidance for the review and analysis of potential environmental risks from use of pesticide products. See Standard Evaluation Procedures (SEP) for Ecological Risk Assessment (EPA 1986). Since 1986 EPA has made many additions and refinements to the basic approach outlined in the SEP. All of

EPA's risk assessment methods have included methodology for an assessment of potential risks to listed species. Refer to the ESPP **Federal Register** Notice (67 FR 71549) for a more detailed description of how EPA assesses the risk to listed species.

EPA requires both new and existing pesticides to be supported by extensive information about the potential ecological risks of the pesticide product. Data requirements appear in EPA regulations at 40 CFR part 158. Studies conducted to generate data for EPA are subject to Good Laboratory Practice requirements that are designed to ensure that the results are reliable and of high quality. See 40 CFR part 160. EPA's scientists carefully review all data submissions and independently evaluate the potential risks of each pesticide. In situations raising novel or challenging scientific issues, EPA generally seeks outside peer review of its scientific assessments.

The Agency requires extensive toxicity and environmental fate data and uses this information, together with field reports of adverse effects on wildlife caused by pesticides and other relevant information, to evaluate the potential hazards to non-target species, including threatened and endangered species, for a pesticide intended for outdoor use. To assess potential hazard to non-target species, EPA requires a basic set of laboratory toxicity studies on an active ingredient using multiple surrogate species of birds, fish, aquatic invertebrates, non-target insects, and plants. In situations where additional, scientifically valid, toxicity data related to effects on wildlife and aquatic organisms are available, EPA will consider them in establishing the toxicity endpoint for risk assessment. It is EPA's policy to conduct risk assessments using the toxicity endpoint from the most sensitive species tested. EPA also requires data from a series of laboratory and field studies of the environmental fate of both the active ingredients in a pesticide product and typical formulations containing the active ingredient. These studies provide data on both the parent active ingredient, as well as its environmental degradates. The Agency combines these data, along with information about how the pesticide product is intended to be used, to develop an estimate of the potential concentrations of residues of the active ingredient and significant environmental degradates in the environment (the Estimated Environmental Concentration or EEC). In order to avoid underestimating risk, EPA makes assumptions designed not to understate potential exposure.

When assessing risks to listed species, EPA evaluates data and risks in a tiered fashion. The Agency compares its toxicity assessment of an active ingredient with the EEC. If the comparison demonstrates that the EEC is well below the amount of active ingredient that would be expected to cause harm to a particular species or critical habitat, EPA would conclude that the use of pesticide products containing that active ingredient would have ''no effect'' on listed species. Most of EPA's focus is on the potential risks from exposure to the active ingredient and its significant environmental degradates. EPA also has information, both on the other ingredients in pesticide products and on the formulations themselves, with which to assess the potential for increased risk. This ingredient- and formulation-specific information and many years of reviewing pesticide products support a general conclusion that inert ingredients in formulations usually do not make more than a negligible contribution to the overall environmental risks posed by a pesticide product formulation. If the initial comparison and subsequent refined assessments indicate that EPA's best estimate of the EEC for the active ingredient and/or significant environmental degradates could have toxic effects on a listed species, then EPA may require the pesticide sponsor to supply additional laboratory and/or field data in order to refine the risk assessment, require changes in the allowable use of the pesticide product that are sufficient to mitigate any potential risk, or determine it necessary to request initiation of consultation with the Services to obtain a Biological Opinion on actions that might be taken relative to reducing risk. Higher tier toxicity data may include studies on the effects of a pesticide on other wildlife species and plants or studies of longer durations of exposure. The Agency may occasionally require higher tier studies to be conducted in the field under simulated or actual use conditions. EPA may also require additional information to improve its estimate of potential exposure. Possible risk mitigation measures include changes in the manner or timing of pesticide applications, the rate or frequency of applications, or geographical restrictions on use.

D. The Endangered Species Act and Federal Agency Consultations with the Services

Section 7 of the ESA imposes obligations upon all Federal agencies whose actions may adversely impact listed species. Of particular relevance to this ANPR, section 7(a)(2) directs all Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce (delegated to the Services), to ensure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat of such species that has been designated as critical (''critical habitat''). 16 U.S.C. 1536(a)(2). In meeting this requirement, each agency is required to use the ''best scientific and commercial data available.'' 16 U.S.C. 1536(a)(2).

The Services adopted joint regulations set forth at 50 CFR part 402, which include procedural requirements. These regulatory provisions require action agencies to consult with the Services on all Federal actions that ''may affect'' a listed species or critical habitat. Consultation may be concluded ''informally'' if the action agency, with written concurrence from the Services, determines that the Federal action under consideration is ''not likely to adversely affect'' a listed species or critical habitat. 50 CFR 402.14(b)(1). ''Formal'' consultation is required on actions that are likely to adversely affect a listed species or critical habitat and when the Services disagree with an action agency's determination that the action is ''not likely to adversely affect'' the species or its critical habitat. During formal consultation, focus is on whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. 50 CFR 402.14(h).

By regulation, the consultation process reviews a variety of potential ''effects'' on listed species and habitat, including direct, indirect, and cumulative effects. ''Direct effects'' are those effects that will immediately flow from the proposed action. ''Indirect effects'' are those that will be caused by the proposed action, will occur later in time, but are still reasonably certain to occur. ''Cumulative effects'' are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the area affected by the proposed action. 50 CFR 402.02. Additionally, examination includes the effects of ''interrelated'' and ''interdependent'' actions. For a detailed explanation of these terms, please refer to the Consultation Handbook jointly published by NMFS and FWS, which further elaborates on the procedures followed by the Services when conducting section 7 consultations.

http://endangered.fws.gov/consultations/s7hndbk/s7hndbk.htm.

During formal consultation, focus is upon whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. 50 CFR 402.14(h).

At the conclusion of formal consultation, the Services will issue a ''biological opinion'' that details the effects of the action on the listed species or critical habitat, and whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. 16 U.S.C. 1536(b)(3)(A). A ''jeopardy'' biological opinion must include reasonable and prudent alternatives, if any are available. Where jeopardy or adverse modification of critical habitat does not exist, the Services must issue an incidental take statement that specifies reasonable and prudent measures necessary to minimize incidental impact. 16 U.S.C. 1536(b)(4). When the terms and conditions of the incidental take statement are followed, all incidental takings that occur are not subject to liability. 16 U.S.C. 1536(o).

Service regulations implementing section 7 also authorize the promulgation of counterpart regulations, that establish alternate consultation procedures for a particular Federal agency. 50 CFR 402.04. Authority to promulgate counterpart regulations acknowledges that in certain instances, the section 7 consultation process can benefit from procedures that differ from the traditional consultation process established by the Services. This ANPR contemplates such regulations.

E. EPA's and the Services' Goals for this ANPR

The Services and EPA are seeking ways to better integrate FIFRA pesticide registration and ESA section 7 consultation processes thereby making the section 7 consultation on pesticides more effective and efficient. Additionally, EPA and the Services are seeking to improve public involvement in and understanding of the consultation process on FIFRA actions. In order to meet these goals, the Services and EPA, in consultation with USDA, will propose counterpart regulations governing section 7 consultation for EPA's regulatory actions, as well as any changes to the FIFRA policies and practices, which may be necessary. In addition, EPA and the Services are considering other procedural modifications to the consultation process for pesticide regulation.

In 1988, Congress addressed the relationship between ESA and EPA's pesticide labeling program. Public Law 100–478, October 7, 1988, amended ESA and required EPA to conduct a study, and to provide Congress with a report of the results, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber commodities. Thus, the clear sense of Congress is that EPA should fulfill its obligation to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users. Accordingly, EPA and the Services are working with USDA in this process.

EPA and the Services share the same overall goal--to improve their capacity to provide needed protection for listed species and their critical habitat in an expedited manner that is not unnecessarily burdensome for pesticide users. The Services and EPA believe that procedures and policies that result in better integration of the ESA consultation process with pesticide regulatory programs--both registration and reregistration--should lead to more efficient production of scientifically sound assessments of risks to listed species and critical habitat. That, in turn, should benefit both the listed species and those affected by EPA's pesticide regulatory programs. Improving the process, including shortening the time frames for ESA review of currently registered pesticide products, would enable EPA to more efficiently implement risk mitigation measures to prevent jeopardy to listed species and to avoid adversely modifying critical habitat. Moreover, many of the applications submitted for registration of pesticide products containing new active ingredients involve pesticide formulations that could have less impacts than the currently registered products with which they would compete. Thus, any improvements in the efficiency and effectiveness of the ESA review process could similarly benefit listed species, as well as more broadly provide benefits for human health and the environment. Finally, given the importance of pesticide use for such essential purposes as production of food and fiber and disease prevention, EPA and the Services believe that improved integration of the FIFRA registration/reregistration and section 7(a)(2) consultation processes, under new counterpart regulations, modification to the FIFRA processes, or through other mechanisms, will be achieved in a way that avoids unnecessary burdens on pesticide users.

In developing a process for conducting future ESA consultations on FIFRA pesticide regulatory actions, the agencies believe it is important to recognize that EPA possesses significant resources and expertise in the field of ecological risk assessment relative to pesticides, while the Services possess the technical and regulatory expertise necessary for consistent administration of ESA. Under FIFRA, EPA makes decisions to allow new or continued use of a pesticide only after carefully examining extensive data on the potential risks that use of a pesticide may pose to non-target wildlife species. In addition, EPA's pesticide regulatory program may require companies to conduct studies needed for a risk assessment. As a result, EPA generally has significant scientific information available with which to evaluate the hazards a pesticide may pose to non-target wildlife. Further, to perform its responsibilities under FIFRA, EPA must maintain a sizeable staff of well-qualified scientists with many years of combined experience in assessing ecological risks. Finally, EPA has performed pioneering work in certain areas of ecological risk assessment, such as the development of exposure models and probabilistic risk assessment techniques.

In addition to its strong scientific data bases and its expertise in the field of ecological risk assessment, EPA's decisions have certain relatively unique characteristics. Pesticide products typically include multiple uses, and can potentially be used in many different parts of the country. Thus, in evaluating a pesticide, EPA considers different locations where the product may be used and whether wildlife or plant species may be affected by such use. This broad scope of review contrasts with actions by Federal agencies that have a narrower geographical scope. In addition, the number of pesticide decisions is also a factor potentially affecting the section 7 consultation process. In a typical year, EPA will make hundreds of decisions regarding pesticide registration, some involving very extensive risk assessments, while others require more limited reviews. For example, in fiscal year 2002, EPA registered 26 new pesticide active ingredients; approved the addition of 720 new uses of previously registered active ingredients on close to 1,500 different crops; and completed more than 4,700 more minor registration actions. EPA also completed reregistration assessments on 36

previously registered active ingredients, and processed over 500 emergency exemption requests in FY 2002. Numbers of actions in most of these categories have risen since FY 2000. The combination of the number and variety of pesticide regulatory decisions EPA makes each year, together with the possible use of pesticide products on multiple sites located in different parts of the country, means that the potential number of consultations about the effects of EPA actions could be far greater than result from any other single Federal regulatory program.

The implementation of a number of the changes discussed in Unit III. would require modification of the existing consultation regulations and FIFRA procedures. We are interested in public comment on all potential changes to the current approach to consultation that could be put into effect through rulemaking or without rulemaking, such as through interagency agreements.

III. Request for Comment

This unit of the ANPR invites public comment on a number of ways in which the current regulations, policies, and practices of the Services and EPA regarding ESA consultations about decisions in the pesticide regulatory program could be modified. Unit III.A. focuses on possible approaches to identifying types of actions that would not require case-by-case consultation between EPA and the Services. Unit III.B. asks for comments on possible changes to the existing framework, while retaining the basic approach of requiring consultation whenever EPA determines that use of a pesticide ''may affect'' protected species. Unit III.C. invites public comment on certain other aspects of the operational relationship between EPA and the Services. The agencies note that the specific approaches described below do not exhaust all of the possible changes that might improve the effectiveness and efficiency of the consultation process. Thus, the agencies invite the public to include comments on other ways to modify the regulations, policies and practices of EPA, FWS, or NMFS to achieve our mutual goals.

Finally, the agencies emphasize that they have made no decisions with respect to pursuing any specific modification discussed below. The agencies will consider public comments about a particular proposed change in light of the following factors, among others: The consistency of the approach with the requirements of ESA and FIFRA; the scientific soundness of the approach; and the impact of the approach on government resources, pesticide users, and others.

A. The Scope of EPA's Consultations on FIFRA Actions Under ESA

1. *Programmatic consultation.* Under existing Service regulations at 50 CFR part 402, the Services and Federal agencies can engage in consultations that address major national programs. There is potential to use this authority to develop a ''programmatic'' approach to consultation on the pesticide registration program. In regulating pesticides under FIFRA, EPA does not develop overall pesticide registration and reregistration programs as, for instance, the Forest Service might develop a forest plan; rather, EPA makes decisions about new and existing pesticide uses on a case-by-case basis, subject to the standards of FIFRA described above. While these decisions are made on a case-by-case basis, in many circumstances these individual registration decisions share common elements. For example, EPA receives hundreds of applications per year for so called ''me-too'' pesticide products that are identical or nearly identical to currently registered pesticides. In addition, some classes of pesticides that are not identical may nonetheless share common exposure or toxicological profiles. Even where pesticides may not share common characteristics, there may be approaches to risk assessment and risk management that are appropriate for identifying and addressing risk concerns to listed species across broad classes of pesticides.

Thus, in circumstances where such commonalities exist, it may be possible for EPA to satisfy some or all of its ESA section 7(a)(2) consultation obligations for individual registration actions by completing what could be described as ''programmatic'' consultations affecting numerous registration and reregistration actions simultaneously. In addition, even where such programmatic consultations are not sufficient to complete the consultation process for certain individual actions, they may serve to improve the consultation process on such actions through the standardization of risk assessment methodologies and alternatives for species protections.

While the Services' current section 7 regulations provide authority for agencies to consult on a group of related actions in this fashion, there may be benefits to using counterpart regulations to establish criteria that would delineate the circumstances under which EPA would be expected to consult with the Services and the circumstances where consultation would not be necessary. Such regulations could identify those practices that EPA would follow to identify and delineate potential adverse effects on listed species and their habitat, as well as the data standards for such evaluations. Such regulations could lead to more efficient use of resources by both the Services and EPA, while at the same time providing the public with an opportunity to participate more fully in the process of protecting listed species.

EPA and the Services welcome comments on this approach and specifically request that commenters consider the following questions in developing their submissions:

- What are the administrative and programmatic advantages and disadvantages of this approach?
- What elements of EPA's pesticide program are particularly amenable to programmatic consultation?
- To what extent, if any, could or should this approach change the consultation process for specific regulatory actions under FIFRA?
- To what extent would it be appropriate to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to listed species in connection with such a ''programmatic'' consultation?
- What are the advantages or disadvantages to implementing this approach through rulemaking?
- What are the advantages or disadvantages to implementing this approach under the Services' existing consultation regulations?
- What would be the appropriate method for addressing issues associated with incidental take under this approach?

2. *Changes to the informal consultation process.* As described in Unit II.D., ESA requires Federal agencies to consult with the Services in meeting their section 7(a)(2) obligations to ensure that agency actions are not likely to jeopardize listed species or destroy or adversely modify any critical habitat of such species. The current consultation regulations at 50 CFR part 402 provide that in circumstances where a Federal agency determines that its actions ''may affect'' a listed species or critical habitat it must engage in consultation with the Services. In circumstances where an agency concludes that an action will have ''no effect'' on listed species or critical habitat, no further consultation is required, and the Federal agency, under such circumstances, has satisfied its section 7(a)(2) obligations regarding such action.

In those circumstances where a Federal agency cannot conclude that its actions will have ''no effect'' on listed species or critical habitat, but can conclude that its actions are ''not likely to adversely affect'' listed species or critical habitat, Service regulations provide that if the relevant Service concurs in writing on that determination the agency need not engage in further, (i.e., formal) consultation with the Service. 50 CFR 402.13. The concurrence approach, in these situations, serves as a Service opinion or interpretation that the agency has satisfied its section 7(a)(2) obligations regarding such actions.

Under these circumstances the Services have determined, by regulation, that formal consultation is unnecessary for individual agency actions in order for Federal agencies to satisfy their section 7(a)(2) obligations. While this regulatory regime currently applies to, and is generally appropriate for, a wide variety of Federal agency actions, there may be circumstances where the mission and expertise of a particular agency, or a particular office within an agency, may lend itself to the development of alternative or additional informal processes. EPA's regulation of pesticides may be one such instance. As explained in Unit II.C., one of EPA's core functions in the regulation of pesticides under FIFRA is the development of extensive ecological risk assessments, including an evaluation of the effects that pesticide use may have on various plant and animal taxa. As a result, EPA may possess sufficient information and analytical expertise to make informed determinations as to whether a pesticide is ''not likely to adversely affect'' a listed species or critical habitat. For this reason, EPA and the Services think it is appropriate to consider whether there is a need for either further consultation or Service concurrence in those situations where EPA determines that use of a pesticide is ''not likely to adversely affect'' listed species or critical habitat.

This ANPR therefore seeks comment on whether to pursue, through counterpart regulations or other mechanisms, either of the two following potential approaches to conducting consultation on pesticide regulatory actions: (1) If EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, no further consultation would be required; or (2) where EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, EPA would continue to consult with the Services but EPA would not need to obtain the written concurrence of the Services to satisfy its section 7(a)(2) obligations.

EPA and the Services welcome comments on these alternate approaches and specifically request that commenters consider the following in developing their submissions:

- The administrative and programmatic advantages and disadvantages of these approaches.
- In connection with such regulations, what, if any, criteria should the Services establish which, if met, would support one or both of the approaches.
- Whether in connection with such regulations it would be appropriate or necessary to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to protected species.
- Whether there are additional changes to the informal consultation process that may be warranted.

3. *Focused review by the Services during consultation.* The immediately preceding alternative explores amendments to the circumstances under which informal consultation would be necessary. This alternative considers potential approaches to consultation that would focus review provided by the Services once formal or informal consultation had been initiated. It is predicated on the assumption that in the development of this rulemaking, EPA's practices and policies would be reviewed and, where necessary revised to ensure that the data and analyses EPA obtains and uses provide the best available information on the effects on threatened and endangered species. As discussed earlier, EPA has extensive information available with which to assess and mitigate potential risks to listed species and their critical habitat and EPA has developed considerable expertise in these areas. Based on this expertise, therefore, in the case of pesticide regulatory actions, this alternative proposes that the Services would rely on EPA's assessment of effects. Thus in the case of pesticide regulatory actions, the Services would rely on EPA's assessment.

When consultation is necessary, an approach would be to provide for a more focused review of EPA pesticide submissions by the Services. This approach would provide for a rebuttable presumption regarding the adequacy of the effects analysis in an EPA request to initiate consultation. There are many potential standards that could be applied to determine whether the effects analysis would be deemed adequate (see 50 CFR 402.14(c)). This ANPR identifies three:

- Whether EPA had considered the most current and best available scientific, commercial, and technical information on listed species and their habitat and that the determinations were not arbitrary and capricious.
- Whether there was clear and convincing information warranting a different conclusion as to the effects of the proposed registration.
- Whether there is substantial evidence to support EPA's effects determinations.

EPA and the Services are seeking comments on this approach and specifically request that commenters consider the following questions in developing their submissions:

- What are the administrative and programmatic advantages and disadvantages of this overall approach?
- What are the administrative and programmatic advantages and disadvantages of specific provisions?
- What are other possible appropriate evidentiary or procedural provisions?
- Should the Services establish criteria which, if met, would justify such an approach?
- Would it be appropriate to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to protected species?

B. Modifications of the Existing Framework Under FIFRA and the ESA to Increase the Effectiveness, Efficiency, and Flexibility of the Existing Interagency Process

1. *Modification of EPA's approach to assessing potential risk to protected species.* EPA routinely receives and evaluates extensive scientific information on the potential hazards of and exposure to pesticide active ingredients as part of its registration and reregistration processes. Unit II.C. contains an overview of this evaluation process and EPA's ESPP Notice describes the risk assessment process in more detail. Please comment on whether there is a need to modify the current assessment process for evaluating the potential risks to protected species, including whether there should be any changes to EPA's data requirements, assessment algorithms, or criteria for judging whether the use of a pesticide poses a potential risk to listed species.

2. *Scope of a consultation.* EPA's registration and reregistration decisions typically involve one or more pesticide products containing a specific active ingredient. A single pesticide product is generally registered for use on multiple crop and/or non-crop sites and may be

applied on any approved site throughout the United States. Thus, a single registration encompasses multiple separate decisions by EPA. The ESA currently requires a Federal agency to ensure that its ''actions'' do not jeopardize protected species or adversely modify critical habitat. The Services' regulations state that ''[a]ny request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given area or a segment of a comprehensive plan.'' 50 CFR 402.14(c). Thus, EPA and the Services have discretion to determine the scope of the regulatory action subject to both formal and informal consultations. Please comment on the advantages and disadvantages of using counterpart regulations or other mechanisms to give EPA and the Services more flexibility to define the scope of EPA's consultation with respect to a specific regulatory action. For example, please comment on whether it would be appropriate to have the ability to define EPA's proposed action in a way that would limit a consultation on a registration decision to: A particular geographical area, a particular ingredient in a pesticide formulation, or a particular use of a pesticide product.

3. *The contents of a consultation package*. The ESA requires that ''each agency shall use the best scientific and commercial data available.'' ESA sec. 7(a)(2). The Services' consultation regulations specify that a written request to initiate formal consultation shall contain:

(1) A description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statements, environmental assessments, or biological assessments prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat. 50 CFR 402.14(c).

The Services' regulations define ''cumulative effects'' to mean ''those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.'' 50 CFR 402.02. The consultation regulations do not establish any requirements with respect to the content of a request for an informal consultation.

Please comment on:

- The meaning of the statutory phrase, ''best scientific and commercial data available,'' with respect to the type of information EPA should be required to include in a review package.
- The advantages and disadvantages of issuing counterpart regulations to modify the existing requirements in 50 CFR 402.14(c).
- Whether the same requirements apply to review packages submitted for informal consultation as for formal consultation or whether informal consultation packages should be subject to any regulatory requirements since they are informal.
- Given that most EPA actions involve multiple pesticide uses that may range from regional to national in scope, what is the most effective and efficient way to address the concept of ''cumulative effects'' as defined under the Services regulations at 50 CFR 402.02?

4. *The time frame for completing formal and informal consultation on pesticide regulatory actions*. The ESA sets a goal of 135 days for concluding a formal consultation, but also contains provisions that allow the action agency and the Services to agree, in certain circumstances, to extend the deadline for completing the consultation. See ESA sec. 7(b). Neither ESA nor the Services' consultation regulations establish a time frame for completion of informal consultations.

Please comment on the advantages and disadvantages of:

- Establishing specific time frames for concluding formal consultations on pesticide regulatory decisions, including the possibility of a shorter time frame and what action by EPA should trigger the start of a time period for formal consultation.
- Establishing specific time frames for concluding informal consultations on pesticide regulatory actions and what action by EPA should trigger the start of a time period for informal consultation.
- Defining specific circumstances under which the time frames should be extended and what those circumstances might be.

5. *Identify and establish procedures for dealing with an ''emergency'' for purposes of emergency consultation and other expedited review*. The Services' consultation regulations contain provisions allowing consultation to be conducted in an expedited manner in ''emergency circumstances.'' 50 CFR 402.05. This provision applies to ''situations involving acts of God, disasters, casualties, national defense or security emergencies, etc.'' The regulations state that expedited consultation may be conducted in any manner consistent with ESA, and that formal consultations ''shall be initiated as soon as practicable after the emergency is under control.'' Under FIFRA, EPA may issue exemptions to States or Federal agencies to allow the use of an unregistered pesticide when ''emergency conditions exist which require such exemption.'' FIFRA sec. 18.

Please comment on whether these and other types of regulatory actions taken by EPA's pesticide programs should be considered ''emergencies'' that would justify conducting any required ESA consultation in an expedited manner. For example, if consultation with the Services were required, should emergency consultation provisions apply to:

- Petitions for emergency exemptions under FIFRA sec. 18?
- Notifications to EPA of State issuance of ''special local needs'' registrations under FIFRA sec. 24(c)?
- Other circumstances giving rise to a need for expedited review?

Are there any circumstances where no review by the Services is appropriate, for example, when the action is taken to address a public health emergency as described in 40 CFR part 166, under FIFRA?

6. *Clarify the role of the Services*. As discussed in Unit II.D., ESA and existing consultation regulations describe the role that the Services play in providing advice and opinions on the impact of agency actions on protected species and their critical habitat.

What are the advantages and disadvantages of using counterpart regulations or other mechanisms to establish additional responsibilities for the Services, for example, by specifying that the Services should assist EPA in developing the information base for consultation or by specifying the types of information that the Services should provide to EPA? What other responsibilities, if any, should the Services assume? Should counterpart regulations (or some other mechanism) establish a process that a Service follows to ensure that, when different parts of its organization issue Biological Opinions on the same pesticide and/or species, its Biological Opinions are consistent? If so, how should that process operate?

7. *Clarify the term ''applicant'' and the participation afforded to applicants*. The current consultation regulations define the term ''applicant,'' as a person ''who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.''

50 CFR 402.02. The regulations provide that during formal consultation, an applicant shall have an opportunity to submit information; the Service will discuss with the Federal Agency and the applicant the Service's review and evaluation of the action as well as the basis for any finding in the Biological Opinion and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) and the applicant may request a copy of, and comment upon, any draft Biological Opinion requested from the Service by the Federal Agency before it is issued in final form by the Service. 50 CFR 402.14.

Should the role outlined in current regulations for an ''applicant'' be retained in counterpart regulations. If so, how should it be applied with respect to pesticide regulatory actions and what procedural rights should such an ''applicant'' have? At what points in the consultation process should the general public have an opportunity to participate?

8. *Clarify and improve the role of States and Tribes and other potential non-Federal representatives.* The current consultation regulations state that a Federal agency may designate a non-Federal representative to prepare biological evaluations and/or to conduct informal consultation with the Services. 50 CFR 402.08. While the regulations do not specify who may (or may not) act as a non-Federal representative, they do indicate that, in some circumstances, an ''applicant'' may be a non-Federal representative.

Please comment on the circumstances, if any, that pesticide companies could or should be designated as a non-Federal representative. In addition, please comment on whether, in view of the role that States and Tribes play in the enforcement of EPA regulatory decisions under FIFRA, States or Tribes could or should be designated as non-Federal representatives.

Should any special or additional procedures be established to provide greater participation of States and Tribes in the consultation process, either as a non-Federal representative or in another capacity?

9. *Fees.* A substantial increase in the number or complexity of consultations between EPA and the Services will require a corresponding increase in agency resources.

Please comment on whether it would be appropriate to charge fees to offset the added expenditures that would be necessary to conduct such consultations. Who should pay such fees, and how should the amount of any fee be determined?

10. *Process for elevating and resolving disagreements between EPA and the Services.* Neither ESA nor the current consultation regulations prescribe how an action agency and the Services will resolve disagreements arising under ESA. EPA and the Services, however, have addressed this issue with respect to consultations about two of EPA's regulatory programs involving water. See Memorandum of Agreement, 66 FR 11202, February 22, 2001.

Please comment on the advantages and disadvantages to using counterpart regulations or some other mechanism to establish procedures for expedited resolution of disagreements between the Services and EPA.

C. Other Programmatic Aspects of the Consultation Process

EPA's ESPP Notice has invited public comment on the most appropriate approach to structure consultations about the potential impacts of pesticides on listed species. The ESPP Notice identified several possible approaches: Consultation on a pesticide-by-pesticide basis; on a geographically defined site-by-site basis; on a crop-by-crop basis; or a species-by-species basis. See 67 FR 71549, December 2, 2002.

In addition to issues about the structure of consultations, EPA and the Services are interested in issues relating to establishing priorities for such consultations. In view of the scope of the pesticide regulatory program, EPA and the Services think the number of consultations that may be needed in the foreseeable future could involve substantial resources. Moreover, given the number of pesticides and their potentially widespread and overlapping uses, the agencies foresee that there could be a large degree of potentially redundant effort unless the consultation process is carefully managed to achieve the most efficient use of limited resources. The Services and EPA therefore invite comment on any additional approaches that might improve the overall consultation process. In particular, the agencies invite comments on the feasibility and usefulness of developing a comprehensive, priority-based schedule for completing any necessary consultations. If such a schedule would be appropriate, how should the Services and EPA determine which consultations should receive highest priority? What role, if any, should the public have in forming the priorities for consultation? How should any priority scheme for endangered species determinations relate to existing schedules for reregistration under FIFRA?

IV. Regulatory Assessment Requirements

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this ANPR is a ''significant regulatory action'' under section 3(f) of the Executive Order, because it raises ''novel legal or policy issues arising out of legal mandates.'' The Agency therefore submitted this ANPR to OMB for the 10–day review period afforded under this Executive Order. Any changes made in response to OMB comments during that review have been documented in the public docket as required by the Executive Order.

Since this ANPR does not impose any requirements, and instead seeks comments and suggestions for the Agency to consider in developing a subsequent notice of proposed rulemaking, the various other review requirements that apply when an agency imposes requirements do not apply to this ANPR.

As a part of your comments on this document, you may include any comments or information that you have regarding these requirements. In particular, any comments or information that would facilitate the Agency's assessment of the potential impact of a procedural rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*). The Agency will consider such comments during the development of the notice of proposed rulemaking as it takes appropriate steps to address any applicable requirements.

List of Subjects in 50 CFR Part 402

Endangered species, Environmental protection, Pesticides.

Dated: January 9, 2003,

William T. Hogarth.

Assistant Administrator, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

Dated: January 8, 2003,

Craig Manson.

Assistant Secretary for Fish and Wildlife and Parks, U.S. Department of the Interior.

Dated: January 21, 2003,

Christine T. Whitman.

Administrator, U.S. Environmental Protection Agency.

[FR Doc. 03–1661 Filed 1–23–03; 8:45 am]

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Federal Register

Friday,
January 24, 2003

Part X

Department of Justice

Immigration and Naturalization Service

8 CFR Part 103

Adjustment of Immigration Benefit Application Fees; Interim Rule

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 103

[INS No. 2257–03]

RIN 1115–AG96

Adjustment of Immigration Benefit Application Fees

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Interim rule with request for comments.

SUMMARY: This rule adjusts the immigration benefit application fee schedule by subtracting the applicable amount of surcharges used for asylum and refugee services, fee exemptions and fee waivers to comply with section 457 of the Homeland Security Act of 2002, Public Law 107–296. Fees collected from persons filing immigration benefit applications are deposited into the Immigration Examinations Fee Account (IEFA) and used to recover the full cost of processing immigration benefit applications and associated administrative costs. Federal guidelines require the Immigration and Naturalization Service (Service or INS) to establish and collect fees to recover the full costs of processing immigration benefit applications.

DATES: *Effective date:* This rule is effective January 24, 2003.

Comment date: Written comments must be submitted on or before March 25, 2003.

ADDRESSES: Please submit written comments to the Director, Regulations and Forms Services Division, Immigration and Naturalization Service, 425 I Street NW., Room 4034, Washington, DC 20536. To ensure proper handling, please reference INS Number 2257–03 on your correspondence. You may also submit comments electronically at *insregs@usdoj.gov.* When submitting comments electronically, you must include INS No. 2257–03 in the subject box so that your comments can be properly routed to the appropriate office. Comments are available for public inspection at the above address by calling (202) 514–3291 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Paul Schlesinger, Chief, Immigration Services Branch, Office of Budget, Immigration and Naturalization Service, 425 I Street NW., Room 5307, Washington, DC 20536, telephone (202) 514–3410.

SUPPLEMENTARY INFORMATION:

What Legal Authority Does the Service Have To Charge Fees?

A. Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriation Acts of 1989 and 1991

With reference to the fees for applications and petitions, the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriation Act, 1989, Public Law 100–459, sec. 209, 102 Stat. 2186, 2203 (October 1, 1988), authorized the Service to prescribe and collect fees to recover the cost of providing certain immigration and naturalization benefits. That law also authorized the establishment of the IEFA in the Treasury of the United States. All revenue from fees collected for immigration and naturalization benefits are deposited in the IEFA and remain available to provide immigration and naturalization services. 8 U.S.C. 1356(n).

In subsequent legislation, the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1991, Public Law 101–515, sec. 210(d), 104 Stat. 2101, 2121 (November 5, 1990), Congress further provided that ''fees for providing adjudication and naturalization services may be set at a level that will ensure recovery of the full costs of providing all such services, including the costs of similar services provided without charge to asylum applicants or other immigrants. Such fees may also be set at a level that will recover any additional costs associated with the administration of the fees collected.'' 8 U.S.C. 1356(m).

The House Conference Report to the bill, entitled ''Making Appropriations for the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies For the Fiscal Year Ending September 30, 1996, and For Other Purposes,'' H.R. Conf. Rep. No. 104–378, at 82 (1995), directs the Service to fund the cost of the Cuban-Haitian Entrant Program from the IEFA. The Report states, ''(t)he conferees have also agreed that the activities related to the resettlement of Cubans and Haitians should be transferred to the * * * Service and that the costs of these activities should be supported by the [IEFA].'' *Id.*

In a final rule effective October 13, 1998, except the Form N–400, which took effect on January 15, 1999, the Service raised the majority of fees to recover the full costs of processing immigration benefit applications, and added a ''surcharge'' setting the fees at a level sufficient to fund the processing of asylum and refugee applications as well as those immigration benefit applications processed at no charge to applicants/petitioners.

What Is the Impact of Section 457 of the Homeland Security Act on the Current Fee Structure?

In section 457 of the Homeland Security Act of 2002, Congress provided that ''Section 286(m) of the Immigration and Nationality Act (8 U.S.C. 1356(m)) is amended by striking ''services, including the costs of similar services provided without charge to asylum applicants or other immigrants.'' and inserting ''services.''. The deletion of this language has the effect of repealing the statutory basis for surcharges. The Service is, therefore, required to reduce immigration benefit application fees by an average of $50, or 25%, for the surcharges applied to the majority of immigration benefit applications as stated in 63 FR 1775 (proposed rule January 12, 1998). The surcharge amount (as well as the costs of processing immigration benefit applications) was subsequently increased by inflation factors as per 66 FR 65811 (final rule December 21, 2001).

The following table displays the surcharges per application for asylum and refugee services, and for fee exemptions and fee waivers (adjusted for inflation).

TABLE 1.—SURCHARGES PER IMMIGRATION BENEFIT APPLICATION

Form No.	Description	Asylum/ refugee	Fee exemptions/ waivers	Total
I–17	Petition for Approval of School for Attendance by Nonimmigrant Student.	$34.76	$27.85	$62.61
I–90	Application to Replace Permanent Resident Card	19.29	15.46	34.75

TABLE 1.—SURCHARGES PER IMMIGRATION BENEFIT APPLICATION—Continued

Form No.	Description	Asylum/ refugee	Fee exemptions/ waivers	Total
I–102	Application for Replacement/Initial Nonimmigrant Arrival/Departure Record.	15.24	12.21	27.45
I–129	Petition for A Nonimmigrant Worker	18.81	15.08	33.89
I–129F	Petition for Alien Fiancé(e)	16.38	13.12	29.50
I–130	Petition for Alien Relative	19.11	15.32	34.43
I–131	Application for Travel Document	16.50	13.22	29.72
I–140	Immigrant Petition for Alien Worker	19.88	15.92	35.80
I–191	Application for Permission to Return to an Unrelinquished Domicile	29.45	23.59	53.04
I–192	Application for Advance Permission to Enter as a Nonimmigrant	29.45	23.59	53.04
I–193	Application for Waiver of Passport and/or Visa	29.45	23.59	53.04
I–212	Application for Permission to Reapply for Admission into the U.S. After Deportation or Removal.	29.45	23.59	53.04
I–485	Application to Register Permanent Residence or to Adjust Status	38.53	30.88	69.41
I–526	Immigrant Petition by Alien Entrepreneur	60.85	48.75	109.60
I–539	Application to Extend/Change Nonimmigrant Status	20.94	16.77	37.71
I–600/600A	Petition to Classify Orphan as an Immediate Relative/Application for Advance Processing or Orphan Petition.	70.79	56.72	127.51
I–601	Application for Waiver of Grounds of Excludability	29.45	23.59	53.04
I–612	Application for Waiver of the Foreign Residence Requirement	29.45	23.59	53.04
I–751	Petition to Remove the Conditions on Residence	22.01	17.64	39.65
I–765	Application for Employment Authorization	17.92	14.36	32.28
I–817	Application for Family Unity Benefits	20.92	16.76	37.68
I–824	Application for Action on an Approved Application or Petition	20.65	16.54	37.19
I–829	Petition by Entrepreneur to Remove Conditions	60.69	48.63	109.32
N–400	Application for Naturalization	39.77	31.87	71.64
N–565	Application for Replacement Naturalization Citizenship Document	23.55	18.87	42.42
N–600	Application for Certification of Citizenship	28.32	22.69	51.01
N–643	Application for Certificate of Citizenship in Behalf of an Adopted Child.	22.06	17.67	39.73

The following table displays the new immigration benefit application fees, minus the surcharge (rounded to the nearest $1.00).

TABLE 2.—CURRENT VERSUS NEW IMMIGRATION BENEFIT APPLICATION FEES

Form No.	Description	New fee	Current fee	Change
I–17	Petition for Approval of School Attendance by Nonimmigrant Student.	$517	$580	($63)
I–90	Application to Replace Permanent Resident Card	95	130	(35)
I–102	Application for Replacement/Initial Nonimmigrant Arrival/Departure Record.	73	100	(27)
I–129	Petition for A Nonimmigrant Worker	96	130	(34)
I–129F	Petition for Alien Fiancé(e)	81	110	(29)
I–130	Petition for Alien Relative	96	130	(34)
I–131	Application for Travel Document	80	110	(30)
I–140	Immigrant Petition for Alien Worker	99	135	(36)
I–191	Application for Permission to Return to an Unrelinquished Domicile	142	195	(53)
I–192	Application for Advance Permission to Enter as a Nonimmigrant	142	195	(53)
I–193	Application for Waiver of Passport and/or Visa	142	195	(53)
I–212	Application for Permission to Reapply for Admission into the U.S. After Deportation or Removal.	142	195	(53)
I–485	Application to Register Permanent Residence or to Adjust Status	186	255	(69)
I–526	Immigrant Petition by Alien Entrepreneur	290	400	(110)
I–539	Application to Extend/Change Nonimmigrant Status	102	140	(38)
I–600/600A	Petition to Classify Orphan as an Immediate Relative/Application for Advance Processing or Orphan Petition.	332	460	(128)
I–601	Application for Waiver of Grounds of Excludability	142	195	(53)
I–612	Application for Waiver of the Foreign Residence Requirement	142	195	(53)
I–751	Petition to Remove the Conditions on Residence	105	145	(40)
I–765	Application for Employment Authorization	88	120	(32)
I–817	Application for Family Unity Benefits	102	140	(38)
I–824	Application for Action on an Approved Application or Petition	103	140	(37)
I–829	Petition by Entrepreneur to Remove Conditions	286	395	(109)
N–400	Application for Naturalization	188	260	(72)
N–565	Application for Replacement Naturalization Citizenship Document	113	155	(42)
N–600	Application for Certification of Citizenship	134	185	(51)
N–643	Application for Certificate of Citizenship in Behalf of an Adopted Child.	105	145	(40)

What Is the Impact of section 457 of the Homeland Security Act on Current Programs?

The Service recognizes that this statutory amendment has the effect of terminating the existing source of funding for the asylum and refugee programs and, accordingly, will impair the Service's ability to adjudicate applications for these programs. This amendment also terminates the existing source of funding for the adjudication of other applications for which the Service has granted a fee waiver under the relevant standards, thereby eliminating the ability of the Service to grant fee waivers and exemptions. However, the Service has no choice in taking this action to revise the current fee schedule because Congress has mandated that result, effective January 24, 2003.

Good Cause Exception

This interim rule is effective on January 24, 2003, although the Service invites post promulgation comments and will address any such comments in a final rule. The Service finds that good cause exists to adopt this rule without the prior notice and comment period and delayed effective date ordinarily required by 5 U.S.C. 553(b) and (d), since section 457 of the Homeland Security Act of 2002, Public Law 107–296 takes effect on January 24, 2003.

Regulatory Flexibility Act

The Acting Commissioner, Immigration and Naturalization Service, in accordance with 5 U.S.C. 605(b), has reviewed this regulation and by approving it has determined that this rule will not have a significant economic impact on a substantial number of small entities. The majority of applications and petitions are submitted by individuals and not small entities as that term is defined in 5 U.S.C. 601(6).

Although the Service acknowledges that a number of small entities, particularly those filing business-related applications and petitions, such as Form I–140, Immigrant Petition for Alien Worker; Form I–526, Immigrant Petition by Alien Entrepreneur; and Form I–829, Petition by Entrepreneur to Remove Conditions, may be affected by this rule, the rule will have a positive impact since the Service will be reducing the costs of petitions and applications.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is considered by the Department of Justice to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. Accordingly, this rule has been submitted to the Office of Management and Budget (OMB) for review.

The Service has assessed both the costs and benefits of this rule as required by section 1(b)(6) of Executive Order 12866 and has made a determination that the Service has no alternative other than to eliminate the surcharge in order to comply with section 457 of Public Law 107–296.

Executive Order 13132

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. Therefore, in accordance with section 6 of Executive Order 13132, the Department of Justice has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988: Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

This rule requires that the fees for application and petition forms identified in this interim rule be reduced to comply with section 457 of Public Law 107–296. Since a reduction of these fees will reduce the cost burden on the public the Service has submitted the required Paperwork Reduction Change Worksheet (OMB–83C) to the Office of Management and Budget (OMB) reflecting the new fees and cost burdens on the public, and OMB has approved the changes.

To ensure that the public is fully aware of these changes the new fees will be highlighted on the Services Web site at: *http://www.ins.usdoj.gov.*

List of Subjects in 8 CFR Part 103

Administrative practice and procedure, Authority delegations (government agencies), Freedom of Information, Privacy, Reporting and recordkeeping requirements, Surety bonds.

Accordingly, part 103 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS; AVAILABILITY OF SERVICE RECORDS

1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 552, 552(a); 8 U.S.C. 1101, 1103, 1304, 1356; 31 U.S.C. 9701; E.O. 12356, 47 FR 14874, 15557; 3 CFR, 1982 Comp., p.166; 8 CFR part 2.

2. Section 103.7(b)(1) is amended by revising the entries for the following forms, to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

* * * * *

Form I–17. For filing a petition for school approval or recertification—$517 plus $350 per additional campus listed on Form I–17B.

* * * * *

Form I–90. For filing an application for a Permanent Resident Card (Form I–551) in lieu of an obsolete card or in lieu of one lost, mutilated, or destroyed, or for a change in name—$95.

* * * * *

Form I–102. For filing a petition for an application (Form I–102) for Arrival/Departure Record (Form I–94) or Crewman's Landing (Form I–95), in lieu of one lost, mutilated, or destroyed—$73.

Form I–129. For filing a petition for a nonimmigrant worker, a base fee of $96. For filing an H–1B petition a base fee of $96 plus an additional $1,000 fee in a single remittance of $1,096. The remittance may be in the form of one or two checks (one in the amount of $1,000 and the other in the amount of $96). Payment of this additional $1,000 fee is not waivable under § 103.7(c)(1). Payment of this additional $1,000 fee is not required if an organization is exempt under § 214.2(h)(19)(iii) of this chapter, and this additional $1,000 fee also does not apply to certain filings by any

employer as provided in § 214.2(h)(19)(v) of this chapter.

Form I–129F. For filing a petition to classify nonimmigrant as fiancée or fiancé under section 214(d) of the Act—$81.

Form I–130. For filing a petition to classify status of alien relative for issuance of immigrant visa under section 204(a) of the Act—$96.

Form I–131. For filing an application for travel documents—$80.

Form I–140. For filing a petition to classify preference status of an alien on the basis of profession or occupation under section 204(a) of the Act—$99.

* * * * *

Form I–191. For filing applications for discretionary relief under section 212(c) of the Act—$142.

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Form I–212. For filing an application for permission to reapply for an excluded, deported or removed alien, an alien who has fallen into distress, an alien who has been removed as an alien enemy, or an alien who has been removed at government expense in lieu of deportation—$142.

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Form I–485. For filing an application for permanent resident status or creation of a record of lawful permanent residence—$186 for an applicant 14 years of age or older; $160 for an applicant under the age of 14 years; no fee for an applicant filing as a refugee under section 209(a) of the Act.

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Form I–526. For filing a petition for an alien entrepreneur—$290.

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Form I–601. For filing an application for waiver of ground of inadmissibility under section 212(h) or (i) of the Act. (Only a single application and fee shall be required when the alien is applying simultaneously for a waiver under both those subsections.)—$142.

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* * * * *

Dated: January 23, 2003.

Michael J. Garcia,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 03–1853 Filed 1–23–03; 11:21 am]

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This is a continuing list of public bills from the current

session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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H.R. 11/P.L. 108–3

National Flood Insurance Program Reauthorization Act of 2003 (Jan. 13, 2003; 117 Stat. 7)

Last List January 14, 2003

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